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PRESCRIPTION DRUG MARKETING ACT OF 1987

HEARING

BEFORE THE

SUBCOMMITTEE ON INTERNATIONAL TRADE

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

S. 368

JUNE 15, 1987

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE

78-906 WASHINGTON : 1988

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U.S. Government Printing Office, Washington, DC 20402

S361-14

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PRESCRIPTION DRUG MARKETING ACT OF 1987

MONDAY, JUNE 15, 1987

U.S. SENATE,
SUBCOMMITTEE ON INTERNATIONAL TRADE,
COMMITTEE ON FINANCE,
Washington, DC.

The committee was convened, pursuant to notice, at 2:12 p.m. in room SD–215, Dirksen Senate Office Building, the Honorable Spark M. Matsunaga (chairman) presiding.

Present: Senator Matsunaga.

[The press release announcing the hearing follows:]

[Press release H–52, June 10, 1987]

INTERNATIONAL TRADE SUBCOMMITTEE CHAIRMAN MATSUNAGA ANNOUNCES HEARING ON S. 368, THE PRESCRIPTION DRUG MARKETING ACT OF 1987

WASHINGTON, DC—Senator Spark Matsunaga (D., Hawaii), Chairman of the Finance Committee's Subcommittee on International Trade, announced Wednesday that the Subcommittee will hold a hearing on Monday, June 15, 1987, at 2:00 p.m. in Room SD–215 of the Dirksen Senate Office Building on S. 368, the Prescription Drug Marketing Act of 1987.

The purpose of S. 368 is to (1) ban the reimportation of drugs manufactured in the United States and exported, unless the importer is the U.S. manufacturer; (2) prohibit the sale or resale of drug samples; (3) regulate the distribution of drug samples; (4) regulate the wholesale distribution of drugs; and (5) provide penalties for the violation of these prohibitions and regulations.

Senator MATSUNAGA. The Subcommittee on International Trade will come to order. Today the Subcommittee on International Trade of the Committee on Finance will be holding a hearing on S. 368 and its house-passed companion bill, H.R. 1207, both of which are designed to remedy one of the most pernicious problems facing the American consumer today: prescription drug diversion.

The American system of testing and manufacturing pharmaceuticals is the safest in the world; yet, the consumer purchasing a prescription drug can no longer do so in full confidence that such drugs will be safe and effective.

Loopholes in the distribution system permit prescription drugs to be diverted out of the normal distribution chain into a gray market or diversion market. Drugs in the diversion market may be shipped all over the world, mishandled, mislabeled, improperly stored, and even counterfeited. Subsequently they are resold to unsuspecting wholesalers or retail pharmacists and reach the consumer in that manner.

Today's hearing will shed further light on drug diversion and how the diversion market works. In addition to protecting consum-

ers from drugs which may be totally ineffective or even harmful, The Prescription Drug Marketing Act will protect reputable business people from the unfair practices of the drug diverters. I am pleased to note that the bill has widespread and enthusiastic support among pharmacists and among pharmaceutical manufacturers; and we will hear from them today also.

The Prescription Drug Marketing Act would amend the Federal Food, Drug and Cosmetic Act to close loopholes in the pharmaceutical distribution system. First, it would prohibit the reimportation of American-made drugs sold overseas. Second, it would prohibit the selling or trading of drug samples intended for use by licensed medical practitioners. And finally, it would prohibit resales of prescription drugs purchased by hospitals and other health care facilities.

The bill would also strengthen the penalties for violations of the Federal Food, Drug and Cosmetic Act.

Now, without further ado, I will be happy to hear from the first panel. Our first panel consists of witnesses from the Attorney General's Office. We have Mr. Robert L. Barr, Jr., the United States Attorney for the Northern District of Georgia; Ms. Gale McKenzie, Assistant U.S. Attorney; Mr. Richard Allen, a Senior Agent for the Drugs and Narcotics Agency in Atlanta, Georgia; and we have also Mr. Jeffery J. Jamar, Chief of the White-Collar Crimes Section of the Criminal Investigations Division of the Federal Bureau of Investigation.

For the last several years, the U.S. Attorney's office in Georgia, with the assistance of the FBI and the Georgia State Drugs and Narcotics Agency, has been investigating and prosecuting drug diversion cases involving the violation of Federal wire and mail fraud statutes and Federal conspiracy statutes. This panel of witnesses will define drug diversion for the subcommittee and describe the dimensions of the problem.

Mr. Barr, we will be happy to hear from you, and I commend you and your staff for your efforts to protect the consumer and prosecute white collar crime. You may begin.

STATEMENT OF ROBERT L. BARR, JR., U.S. ATTORNEY, NORTHERN DISTRICT OF GEORGIA, ATLANTA, GA, ACCOMPANIED BY GALE McKENZIE, ASSISTANT U.S. ATTORNEY, NORTHERN DISTRICT OF GEORGIA; AND JOHN K. COFFEY, FEDERAL BUREAU OF INVESTIGATION, ATLANTA, GA

Mr. BARR. Thank you, Mr. Chairman. It is a pleasure to be up here from Atlanta today to share in the subcommittee's invitation and hospitality to provide some background on a series—an ongoing series—of very important investigations and prosecutions that initiated in the Northern District of Georgia about four years ago.

My predecessor in the position of United States Attorney, the Honorable Larry Thompson, came up and appeared before a similar subcommittee over on the House side in late 1985, Mr. Chairman; and at that time, to give the subcommittee some indication of the massiveness of this problem—at that time—early on in this investigation and prosecutorial process, we had either under indictment or pursuant to information some 40-odd defendants. We now

have well over 80 defendants. The cases are ongoing. As a matter of fact, when we get back to Atlanta, by virtue of the publicity surrounding this subcommittee's work, we probably will have more cases come into the office.

The drugs that are before the chairman, which will be described in greater detail by the FBI and Mr. Rick Allen from the State of Georgia drug agency are really but the tip of the iceberg, as are the prosecutions, although massive, but the tip of what we believe is the iceberg of illegal drug diversion with the ultimate problem being the consumers of this country, not only here in Washington and in Georgia, but in every State of the Union, not being able to rely on the integrity of the prescription drugs which they take.

If I now, Mr. Chairman, may proceed to my prepared remarks?

Senator MATSUNAGA. Please.

Mr. BARR. It is a pleasure to appear before you today and report the results of an important and continuing investigation and prosecution undertaken by the FBI and the United States Attorney's office for the Northern District of Georgia. The investigation involved in Atlanta-based FBI undercover operations is code-named "Pharmoney." The FBI and the U.S. Attorney's Office were ably assisted in the investigation by the Georgia Drugs and Narcotics Agency and the Georgia Board of Pharmacy.

The investigation and resulting prosecutions, which parenthetically are continuing even as we meet here today, covered a variety of illegal practices which are sometimes referred to as drug diversion and drug adulteration and misbranding. I believe this investigation and resulting prosecutions are important for two reasons.

First, they have served in a significant way to protect the American public's absolute right to receive safe and high-quality prescription drugs. They also serve to put on notice to others who might be tempted to try such illegal schemes that the fraudulent procurement of drugs and the adulteration and misbranding of drugs will not be tolerated and that such practices will be investigated and prosecuted to the fullest extent of the Department of Justice in cooperation with State law enforcement officials.

This series of cases, if I may digress for just a moment, Mr. Chairman, is probably the best example that I have seen in my years as an attorney of the cooperative effort between Federal prosecutors, Federal investigators, and State investigators in putting together very complex cases. To date, well over 30 individuals and companies have been charged in criminal investigations with violating Federal wire fraud, mail fraud, conspiracy, interstate transportation of drugs obtained by fraud, and drug adulteration and misbranding statutes.

These defendants have pled guilty. Over half have received periods of incarceration, some as much as five years in jail. Significant amounts of community service and fines up to half a million dollars were made a condition of those sentences which were probated. Our investigation is continuing, and more similar charges are forthcoming.

These white collar criminal prosecutions have received a very high priority in this office, and one senior assistant, the United States Attorney, Ms. Gale McKenzie to my left, has been assigned almost full time to the investigation for a period of about 20

months. This is consistent with the directive of Attorney General Meese's Economic Crime Council, of which I am a member, that all 93 United States Attorneys give high priority to white collar crime law enforcement initiatives.

We are also pleased that many of these convicted defendants received sentences which involved periods of incarceration. It is the policy of the Department of Justice to seek and not oppose jail time for white collar violators in appropriate cases and in a manner consistent with the efficient administration of justice and the responsible allocation of prosecutive resources.

Pursuant to our obligations under the Victim-Witness Protection Act enacted by Congress in 1982, we filed victim impact statements with the courts in the Northern District of Georgia in all cases. I will now summarize for you what we have told the courts regarding the deleterious impact of this illegal activity on its collective victims, the American drug consuming public.

Pharmaceutical diversion involves a scheme wherein false and fraudulent representations are made directly and indirectly to drug manufacturers that pharmaceuticals are being purchased for use in hospitals, clinics, nursing homes, export and charity in order to obtain low purchase prices. The drugs so purchased are then diverted from such use to resale at substantial profit for ultimate dispensing to consumers with prescriptions.

Some defendants in these cases were involved in actual misrepresentations; others knowingly purchased drugs originally obtained under such false and fraudulent pretenses. In addition to defrauding the pharmaceutical manufacturers and the drug-consuming public of money and property, such diversion jeopardizes the ability to trace drugs in the event of a product recall since the drugs are not used by the entity for which they were ordered.

Efforts to avoid detection often result in diverted drugs being drop-shipped across the country or abroad and stored in warehouses, garages, attics, basements, ships, and loading docks not subject to inspection where environmental control and sanitary conditions can—to put it mildly—be virtually ignored. Many of these defendants involved in diversion have no State wholesale license which made their purchase and sale of drugs illegal on that basis alone; and of course, their premises were not subject to inspection because the State boards and the FDA charged with that duty were unaware of the activity.

While some individual defendants may not have been fully aware of the specifics of such treatment by others in the distribution system, they did have reason to know that the distribution of diverted drugs is necessarily both complex and offers a less timely delivery to the ultimate consumer than a normal manufacturer-to-wholesaler or to-hospital or to-retailer system.

Furthermore, this secondary distribution system is attractive to those wishing to dispose of stolen, foreign made, counterfeit, or adulterated and misbranded drugs. For example, many diverters identified by the Pharmoney investigation have recently received counterfeit Naprosyn. Some of these diverters received counterfeit birth control pills as far back as 1984.

Every American family is affected not only by the cost of prescription drugs, but also by the medication's integrity or, in this case, the lack thereof. The problem is enormous.

Annual diversions of the drug involved in this investigation from hospitals, nursing homes, clinics, export, and charitable uses amounted to an estimated $1 billion. In fact, the Pharmoney investigation revealed illegal drug diversion and adulteration and misbranding operations in every State except Alaska. Those criminally involved include hospital and nursing home holding companies, individual hospitals, national and regional pharmaceutical wholesalers, national drug store chains, neighborhood pharmacies, clinics, and drug manufacturers' sales representatives, as well as physicians, registered pharmacists, brokers, middle persons, and publicly traded companies. Of course, these defendants were not responsible for this entire amount.

The low purchase prices obtained by the diverters through their false pretenses are not passed on to the ultimate consumers. Instead, the drugs are resold through many levels within the secondary diversion distribution system, with the initial diverter usually doubling his or her money and subsequent purchasers also making substantial profits until the ultimate consumer is given a miniscule discount, if there is any discount at all.

The losses to the manufacturers are passed on to the drug-consuming public through higher prices. However, it is obvious that prescription medications are not items that a consumer can decline to purchase should the price be too high.

In addition, having access to lower priced diverted drugs gives those involved in that illegal activity a competitive advantage over others in the same trading class, a circumstance which is prescribed by the Robinson-Patman Act.

Adulterated and misbranding involves the removal of drugs from their original packaging and labeling under less than good manufacturing practices and the placing of these pills in plastic baggies or other unauthorized containers—sometimes even less sanitary than baggies—without accurate and verifiable lot numbers, expiration dates, and other required data. The FDA has rigid safeguards for the handling and packaging of drugs, including, among other requirements, sterile hand, head, beard, body, and feet coverings in rooms with no windows and having special air filtering systems.

Those who deal in adulterated and misbranded drugs disregard all safeguards considered essential by Congress and by health experts in this country. Drugs were shucked or removed from their original packaging and labeling for a number of reasons, including: they were expired; the identifying stock number on their label caused by their misrepresentation that they were for consumption by the nonpublic sector had to be removed; they were manufactured under Spanish labels without U.S. inspection and controls in Mexico; or they were marked "Sample, Not to be Sold" and had been originally obtained from drug manufacturers under the false and fraudulent pretense that they would be dispensed for promotional purposes free of charge to patients of doctors and clinics for bona fide purposes.

The removal of the word "Sample" imprinted on individual tablets and capsules was accomplished either through scraping with

razor blades or through applications of the chemical Acetone, fingernail polish remover, and rubbing alcohol.

Such scraping of tablets reduced their unit dosage. We believe that millions of these adulterated pills were in fact sold and continue to be sold across the United States for ultimate dispensing to consumers with prescriptions.

Such drugs were stored and resold in open boxes, used paper grocery sacks, cellophane bread wrappers, old soft drink plastic bottles, plastic baggies, and other unauthorized containers. Many of these pills had been expired for over five years.

Electric erasers and silver paint were used to conceal the "Sample" notations of packs of birth control pills. The presence of diverted, adulterated, and misbranded drugs in the prescription drug distribution system is a national problem. At least one drug store in every city, town, and village involved in the FBI investigation was found to be dispensing such medications. These adulterated and misbranded drugs included blood pressure and heart medications as well as thyroid pills, ulcer solutions, birth control pills, and antibiotics—almost any type of noncontrolled prescription medication. Some had been expired for over five years.

The drugs that were not out of date when placed in the plastic baggies were often treated as if they had everlasting potency since the expiration date was no longer printed on the package itself. Many of these sales representatives and doctors did not realize how the samples were treated during the removal from their original packaging and labeling.

Some of the many pharmacists who ultimately dispensed to consumers with prescriptions from baggies and other unauthorized containers had no knowledge of the detailed history of the drugs. This is also true for others in the distribution chain. Many of the defendants in the distribution chain did, in fact, though have such actual knowledge. However, because they were dealing in adulterated and misbranded drugs, all defendants lacked the assurance of sealed stock bottles with original packaging and labeling, lot numbers, expiration dates, and other required data.

They had no assurance that they were not dealing in expired, stolen, Mexican-made, contaminated, or other drugs otherwise harmful to the consumer. In most cases, they were in fact dealing in exactly those sorts of pharmaceuticals.

The victim impact lies in the fact that in addition to defrauding the pharmaceutical manufacturers and drug-consuming public of money and property, product integrity is compromised severely because such adulterated and misbranded drugs cannot be recalled in an emergency and their potency and purity cannot be assured.

This investigation and resulting prosecutions have received widespread public attention. The United States Attorneys Office, the FBI office, and the Georgia Board of Pharmacy have received numerous calls from citizens concerned about the safety of prescription drugs. The courts have also done their job in these cases by sending certain defendants to jail for their transgressions against the consumer and society. These jail sentences serve the all-important function of deterrence.

In closing, I would like to read to you a brief excerpt from the sentencing hearing in one of these Pharmoney cases before the

Honorable Richard C. Freeman of the United States District Court for the Northern District of Georgia, which we believe summarizes both the import and nature of the problem addressed by this investigation and series of prosecutions. In sentencing the defendant in this case to three years in prison, Judge Freeman stated, and I quote:

> I forgot about the diversion count, but that does present some problems because the trial usually ends there. If there is a recall and you have nobody, you don't know who has the drugs. You know they went to a hospital, but the hospital let them go to somebody else, so you don't know where they are.
>
> It is a very serious thing, and I don't think really that the public understands quite yet the seriousness of what has been going on. You or somebody else said in a memo that I read recently, maybe this will shake up the pharmaceutical industry and they will do some things to prevent this thing from happening in the future.
>
> We have, from the standpoint of deterrence, we have not only to think of Mr. X. I don't believe Mr. X will ever be back here again. He wouldn't be back here again on a charge such as this. I agree with you there.
>
> But it does not do good to have the United States Attorney's Office working with the Federal Bureau of Investigation on a great big nationwide program to go out and round up hundreds of people who are doing this sort of thing; and the public gets all aroused and says, this is wonderful. Somebody is spending our tax dollars wisely. They are catching these thieves and these people who are taking advantage of us; and to have some judge come along and give everybody probation.

On a personal note, I would like to express my deep appreciation to Special Agents Carl Christiansen—who is not here with us today—and John Coffey and J. Wright of the FBI. Mr. Coffey is with the Atlanta office. Senior Agent Rick Allen of the Georgia Drugs and Narcotics Agency, who initially brought the pharmaceutical diversion problem to our attention. And to Assistant United States Attorney Gale McKenzie for the very fine job they have all done in the Northern District of Georgia in overseeing the day-to-day details of this ongoing series of investigations and prosecutions. I would also like to commend the subcommittee for its work in bringing to the attention of the American public to the seriousness of the problems associated with drug diversion.

Mr. Chairman, this concludes my prepared statement, and I would like now to introduce to the subcommittee, with its permission, Mr. Jeffrey Jamar, Chief of the White-Collar Crimes Section at the FBI Headquarters. After Mr. Jamar's presentation, I would be pleased to answer any questions members of the subcommittee may have. Thank you, Mr. Chairman.

Senator MATSUNAGA. Mr. Jamar?

Mr. JAMAR. Thank you, Mr. Chairman. I am happy to be able to be here to present the views and experiences of the FBI regarding the diversion of pharmaceuticals.

Senator MATSUNAGA. Incidentally, I forgot to mention at the beginning that we have this traffic light system: green, yellow, and red. Green, of course, you go; yellow, you go like hell; and then, you are supposed to stop, but I was so intrigued by your testimony, Mr. Barr, I just let you keep going. Your written statement will appear in the record as though presented in full. Then, if you could summarize in as close to five minutes as possible, we would appreciate it; but if you go beyond just a few minutes, we will allow that.

So, you may now begin, Mr. Jamar.

[The prepared written statement of Mr. Barr follows:]

STATEMENT OF

ROBERT L. BARR, JR.

UNITED STATES ATTORNEY

NORTHERN DISTRICT OF GEORGIA

BEFORE THE

SUBCOMMITTEE ON INTERNATIONAL TRADE

COMMITTEE ON FINANCE

UNITED STATES SENATE

CONCERNING

DIVERSION OF PRESCRIPTION PHARMACEUTICALS

ON

JUNE 15,1987

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE,

IT IS A PLEASURE TO APPEAR BEFORE YOU TODAY AND REPORT THE RESULTS OF AN IMPORTANT INVESTIGATION AND PROSECUTION UNDERTAKEN BY THE FBI AND THE UNITED STATES ATTORNEY'S OFFICE FOR THE NORTHERN DISTRICT OF GEORGIA. THE INVESTIGATION INVOLVED AN ATLANTA BASED FBI UNDERCOVER OPERATION CODE NAMED "PHARMONEY." THE FBI AND THE U.S. ATTORNEY'S OFFICE WERE ABLY ASSISTED IN THE INVESTIGATION BY THE GEORGIA DRUGS AND NARCOTICS AGENCY AND THE GEORGIA BOARD OF PHARMACY. THE INVESTIGATION AND RESULTING PROSECUTIONS COVERED A VARIETY OF ILLEGAL PRACTICES WHICH ARE SOMETIMES REFERRED TO AS DRUG DIVERSION AND DRUG ADULTERATION AND MISBRANDING.

I BELIEVE THIS INVESTIGATION AND RESULTING PROSECUTIONS ARE IMPORTANT FOR TWO REASONS. FIRST, THEY HAVE SERVED IN A SIGNIFICANT WAY TO PROTECT THE AMERICAN PUBLIC'S ABSOLUTE RIGHT TO RECEIVE SAFE AND HIGH QUALITY PRESCRIPTION DRUGS. THEY ALSO SERVE TO PUT ON NOTICE TO OTHERS WHO MIGHT BE TEMPTED TO TRY SUCH ILLEGAL SCHEMES THAT THE FRAUDULENT PROCUREMENT OF DRUGS AND THE ADULTERATION AND MISBRANDING OF DRUGS WILL NOT BE TOLERATED AND THAT SUCH PRACTICES WILL BE INVESTIGATED AND PROSECUTED TO THE FULLEST EXTENT BY THE DEPARTMENT OF JUSTICE IN COOPERATION WITH STATE LAW ENFORCEMENT OFFICIALS.

RESULTS

TO DATE, OVER 80 INDIVIDUALS AND COMPANIES HAVE BEEN CHARGED IN CRIMINAL INFORMATIONS WITH VIOLATING FEDERAL WIRE FRAUD, MAIL FRAUD, CONSPIRACY, INTERSTATE TRANSPORTATION OF DRUGS OBTAINED BY FRAUD AND DRUG ADULTERATION AND MISBRANDING STATUTES. THESE

DEFENDANTS HAVE PLEAD GUILTY. OVER HALF HAVE RECEIVED PERIODS OF INCARCERATION, SOME AS MUCH AS FIVE YEARS IN JAIL. SIGNIFICANT AMOUNTS OF COMMUNITY SERVICE AND FINES OF UP TO HALF A MILLION DOLLARS WERE MADE A CONDITION OF THOSE SENTENCES WHICH WERE PROBATED. OUR INVESTIGATION IS CONTINUING AND MORE SIMILAR CHARGES ARE FORTHCOMING.

THESE WHITE COLLAR CRIMINAL PROSECUTIONS HAVE RECEIVED A VERY HIGH PRIORITY IN THIS OFFICE AND ONE SENIOR ASSISTANT UNITED STATES ATTORNEY HAS BEEN ASSIGNED ALMOST FULL TIME TO THE INVESTIGATION FOR A PERIOD OF 20 MONTHS. THIS IS CONSISTENT WITH THE DIRECTIVE OF ATTORNEY GENERAL MEESE'S ECONOMIC CRIME COUNCIL, OF WHICH I AM A MEMBER, THAT ALL 93 UNITED STATES ATTORNEYS GIVE HIGH PRIORITY TO WHITE COLLAR CRIME LAW ENFORCEMENT INITIATIVES. WE ARE ALSO PLEASED THAT MANY OF THESE CONVICTED DEFENDANTS RECEIVED SENTENCES WHICH INVOLVED PERIODS OF INCARCERATION. IT IS THE POLICY OF THE DEPARTMENT OF JUSTICE TO SEEK AND NOT OPPOSE JAIL TIME FOR WHITE COLLAR VIOLATORS IN APPROPRIATE CASES AND IN A MANNER CONSISTENT WITH THE EFFICIENT ADMINISTRATION OF JUSTICE AND THE RESPONSIBLE ALLOCATION OF PROSECUTIVE RESOURCES.

VICTIM IMPACT

PURSUANT TO OUR OBLIGATIONS UNDER THE VICTIM-WITNESS PROTECTION ACT ENACTED BY CONGRESS IN 1982, WE FILED VICTIM IMPACT STATEMENTS WITH THE COURTS IN THE NORTHERN DISTRICT OF GEORGIA IN ALL CASES. I WILL NOW SUMMARIZE FOR YOU WHAT WE TOLD THE COURTS REGARDING THE DELETERIOUS IMPACT OF THIS ILLEGAL ACTIVITY ON ITS COLLECTIVE VICTIMS--THE AMERICAN DRUG CONSUMING PUBLIC.

I. PHARMACEUTICAL DIVERSION

PHARMACEUTICAL "DIVERSION" INVOLVES A SCHEME WHEREIN FALSE AND FRAUDULENT REPRESENTATIONS ARE MADE, DIRECTLY AND INDIRECTLY, TO DRUG MANUFACTURERS THAT PHARMACEUTICALS ARE BEING PURCHASED FOR USE IN HOSPITALS, CLINICS, NURSING HOMES, EXPORT AND CHARITIES IN ORDER TO OBTAIN LOW PURCHASE PRICES. THE DRUGS SO PURCHASED ARE THEN "DIVERTED" FROM SUCH USE TO RESALE AT SUBSTANTIAL PROFIT FOR ULTIMATE DISPENSING TO CONSUMERS WITH PRESCRIPTIONS. SOME DEFENDANTS IN THESE CASES WERE INVOLVED IN ACTUAL MISREPRESENTATIONS. OTHERS KNOWINGLY PURCHASED DRUGS ORIGINALLY OBTAINED UNDER SUCH FALSE AND FRAUDULENT PRETENSES.

A. PRODUCT INTEGRITY

IN ADDITION TO DEFRAUDING THE PHARMACEUTICAL MANUFACTURERS AND THE DRUG CONSUMING PUBLIC OF MONEY AND PROPERTY, SUCH "DIVERSION" JEOPARDIZES THE ABILITY TO TRACE DRUGS IN THE EVENT OF A PRODUCT RECALL SINCE THE DRUGS ARE NOT USED BY THE ENTITY FOR WHICH THEY WERE ORDERED. EFFORTS TO AVOID DETECTION OFTEN RESULT IN "DIVERTED" DRUGS BEING DROPPED SHIPPED ACROSS THE COUNTRY OR ABROAD AND STORED IN WAREHOUSES, GARAGES, ATTICS, BASEMENTS, SHIPS, AND LOADING DOCKS NOT SUBJECT TO INSPECTION, WHERE ENVIRONMENTAL CONTROLS AND SANITARY CONDITIONS CAN BE VIRTUALLY IGNORED. MANY OF THESE DEFENDANTS INVOLVED IN "DIVERSION" HAD NO STATE WHOLESALE LICENSE WHICH MADE THEIR PURCHASE AND SALE OF DRUGS ILLEGAL ON THAT BASIS ALONE; AND, OF COURSE, THEIR PREMISES WERE NOT SUBJECT TO INSPECTION BECAUSE THE STATE BOARDS AND THE FDA CHARGED WITH THAT DUTY WERE UNAWARE OF THEIR ACTIVITY.

WHILE SOME INDIVIDUAL DEFENDANTS MAY NOT HAVE BEEN FULLY AWARE OF THE SPECIFICS OF SUCH TREATMENT BY OTHERS IN THE DISTRIBUTION SYSTEM, THEY DID HAVE REASON TO KNOW THAT THE DISTRIBUTION OF "DIVERTED" DRUGS IS NECESSARILY MORE COMPLEX AND OFFERS A LESS TIMELY DELIVERY TO THE ULTIMATE CONSUMER THAN A NORMAL MANUFACTURER-TO WHOLESALER-TO HOSPITAL OR RETAILER SYSTEM. FURTHERMORE, THIS SECONDARY DISTRIBUTION SYSTEM IS ATTRACTIVE TO THOSE WISHING TO DISPOSE OF STOLEN, FOREIGN-MADE, COUNTERFEIT, OR ADULTERATED AND MISBRANDED DRUGS. FOR EXAMPLE, MANY OF THE DIVERTERS IDENTIFIED BY THE PHARMONEY INVESTIGATION HAVE RECENTLY RECEIVED COUNTERFEIT NAPROSYN. SOME OF THESE SAME DIVERTERS RECEIVED COUNTERFEIT BIRTH CONTROL PILLS BACK IN 1984.

B. MONETARY FRAUD

EVERY AMERICAN FAMILY IS AFFECTED NOT ONLY BY THE COST OF PRESCRIPTION DRUGS, BUT ALSO BY THE MEDICATION'S INTEGRITY OR LACK THEREOF. THE PROBLEM IS ENORMOUS. ANNUAL "DIVERSIONS" OF THE DRUGS INVOLVED IN THIS INVESTIGATION FROM HOSPITAL, NURSING HOME, CLINIC, EXPORT AND CHARITABLE USE AMOUNT OF AN ESTIMATED ONE BILLION DOLLARS. IN FACT, THE PHARMONEY INVESTIGATION REVEALED ILLEGAL DRUG DIVERSION AND ADULTERATION AND MISBRANDING OPERATIONS IN EVERY STATE EXCEPT ALASKA. THOSE CRIMINALLY INVOLVED INCLUDE HOSPITAL AND NURSING HOME HOLDING COMPLANIES, INDIVIDUAL HOSPITALS, NATIONAL AND REGIONAL PHARMACEUTICAL WHOLESALERS, NATIONAL DRUGSTORE CHAINS, NEIGHBORHOOD PHARMACIES, CLINICS AND DRUG MANUFACTURERS (I.E. SALES REPRESENTATIVES), AS WELL AS PHYSICIANS, REGISTERED PHARMACISTS, BROKERS, MIDDLEPERSONS, AND PUBLICALLY TRADED COMPANIES. OF COURSE, THESE

DEFENDANTS WERE NOT RESPONSIBLE FOR THIS ENTIRE AMOUNT. THE LOW PURCHASE PRICES OBTAINED BY "DIVERTERS" THROUGH THEIR FALSE PRETENSES ARE NOT PASSED ON TO THE ULTIMATE CONSUMERS. INSTEAD, THE DRUGS ARE RESOLD THROUGH MANY LEVELS WITHIN THE SECONDARY "DIVERSIONARY" DISTRIBUTION SYSTEM WITH THE INITIAL "DIVERTER" USUALLY DOUBLING HIS MONEY AND SUBSEQUENT PURCHASERS ALSO MAKING SUBSTANTIAL PROFITS UNTIL THE ULTIMATE CONSUMER IS GIVEN A MINISCULE DISCOUNT, IF THERE IS ANY DISCOUNT AT ALL. THE LOSSES OF THE MANUFACTURERS ARE PASSED ON TO THE DRUG CONSUMING PUBLIC THROUGH HIGHER PRICES. HOWEVER, IT IS OBVIOUS THAT PRESCRIPTION MEDICATIONS ARE NOT ITEMS THAT A CONSUMER CAN DECLINE TO PURCHASE SHOULD THE PRICE BE TOO HIGH.

C. UNFAIR COMPETITION

IN ADDITION, HAVING ACCESS TO LOWER PRICED "DIVERTED" DRUGS GIVES THOSE INVOLVE IN THAT ILLEGAL ACTIVITY A COMPETITIVE ADVANTAGE OVER OTHERS IN THE SAME TRADING CLASS--A CIRCUMSTANCE WHICH IS PROSCRIBED BY THE ROBINSON-PATMAN ACT.

II. ADULTERATED AND MISBRANDED DRUGS

ADULTERATED AND MISBRANDING INVOLVES THE REMOVAL OF DRUGS FROM THEIR ORIGINAL PACKAGING AND LABELING UNDER LESS THAN GOOD MANUFACTURING PRACTICES, AND THE PLACING OF LOOSE PILLS IN PLASTIC BAGGIES OR OTHER UNAUTHORIZED CONTAINERS WITHOUT ACCURATE AND VERIFIABLE LOT NUMBERS, EXPIRATION DATES, AND OTHER REQUIRED DATA.

THE FDA HAS RIGID SAFEGUARDS FOR THE HANDLING AND PACKAGING OF DRUGS, INCLUDING AMONG OTHER REQUIREMENTS, STERILE HAND, HEAD, BEARD, BODY, AND FEET COVERINGS IN ROOMS WITH NO WINDOWS HAVING

SPECIAL AIR FILTERING SYSTEMS. THOSES WHO DEAL IN ADULTERATED AND MISBRANDED DRUGS DISREGARD ALL SAFEGUARDS CONSIDERED ESSENTIAL BY CONGRESS AND BY HEALTH EXPERTS IN THIS COUNTY.

A. REASONS FOR ADULTERATION AND MISBRANDING

DRUGS WERE "SHUCKED" OR REMOVED FROM THEIR ORIGINAL PACKAGING AND LABELING FOR A NUMBER OF REASONS, INCLUDING: (1) THEY WERE EXPIRED; (2) THE IDENTIFYING STOCK NUMBER ON THEIR LABEL, CAUSED BY THEIR MISREPRESENTATION THAT THEY WERE FOR CONSUMPTION BY THE NON-PUBLIC SECTOR, HAD TO BE REMOVED; (3) THEY WERE MANUFACTURED UNDER SPANISH LABELS, WITHOUT U.S. INSPECTION AND CONTROLS IN MEXICO; OR (4) THEY WERE MARKED "SAMPLE--NOT TO BE SOLD" AND HAD BEEN ORIGINALLY OBTAINED FROM DRUG MANUFACTURERS UNDER THE FALSE AND FRAUDULENT PRETENSE THAT THEY WOULD BE DISPENSED FOR PROMOTIONAL PURPOSES FREE OF CHARGE TO PATIENTS OF DOCTORS AND CLINICS.

THE REMOVAL OF THE WORD "SAMPLE" IMPRINTED ON INDIVIDUAL TABLETS AND CAPSULES WAS ACCOMPLISHED EITHER THROUGH SCRAPING WITH RAZOR BLADES OR THROUGH APPLICATIONS OF THE CHEMICAL ACETONE, FINGERNAIL POLISH REMOVER, AND RUBBING ALCOHOL. SUCH SCRAPING OF TABLETS REDUCED THEIR UNIT DOSAGE. WE BELIEVE THAT MILLIONS OF THESE ADULTERATED PILLS WERE SOLD, AND CONTINUE TO BE SOLD, ACROSS THE UNITED STATES FOR ULTIMATE DISPENSING TO CONSUMERS WITH PRESCRIPTIONS.

SUCH DRUGS WERE STORED AND RESOLD IN OPEN BOXES, USED PAPER GROCERY SACKS, CELLOPHANE BREAD WRAPPERS, OLD SOFT DRINK PLASTIC BOTTLES, PLASTIC BAGGIES AND OTHER UNAUTHORIZED CONTAINERS. MANY OF THESE PILLS HAD BEEN EXPIRED FOR OVER FIVE YEARS. ELECTRIC

ERASERS AND SILVER PAINT WERE USED TO CONCEAL THE SAMPLE NOTATIONS OF PACKS OF BIRTH CONTROL PILLS.

B. NATIONAL SCOPE OF PROBLEM

THE PRESENCE OF DIVERTED, ADULTERATED AND MISBRANDED DRUGS IN THE PRESCRIPTION DRUG DISTRIBUTION SYSTEM IS A NATIONAL PROBLEM. AT LEAST ONE DRUG STORE IN EVERY CITY, TOWN AND VILLAGE INVOLVED IN THE FBI INVESTIGATION WAS FOUND TO BE DISPENSING SUCH MEDICATIONS. THESE ADULTERATED AND MISBRANDED DRUGS INCLUDED BLOOD PRESSURE AND HEART MEDICATIONS, AS WELL AS THYROID PILLS, ULCER SOLUCTIONS, BIRTH CONTROL PILLS AND ANTIBIOTICS--ALMOST ANY TYPE OF NON-CONTROLLED PRESCRIPTION MEDICATION. SOME HAD BEEN EXPIRED FOR OVER FIVE YEARS. THE DRUGS THAT WERE NOT OUT OF DATE WHEN PLACED IN PLASTIC BAGGIES WERE OFTEN TREATED AS IF THEY HAD EVERLASTING POTENCY SINCE THE EXPIRATION DATE WAS NO LONGER PRINTED ON THE PACKAGE.

C. DEFENDANT KNOWLEDGE RE PRODUCT INTEGRITY

MANY OF THESE SALES REPRESENTATIVES AND DOCTORS DID NOT REALIZE HOW THE SAMPLES WERE TREATED DURING THE REMOVAL FROM THEIR ORIGINAL PACKAGING AND LABELING. SOME OF THE MANY PHARMACISTS WHO ULTIMATELY DISPENSED TO CONSUMERS WITH PRESCRIPTIONS FROM BAGGIES AND OTHER UNAUTHORIZED CONTAINERS HAD NO KNOWLEDGE OF THE DETAILED HISTORY OF THE DRUGS. THIS IS ALSO TRUE FOR OTHERS IN THE DISTRIBUTION CHAIN. MANY OF THE DEFENDANTS IN THE DISTRIBUTION CHAIN DID, IN FACT, HAVE SUCH ACTUAL KNOWLEDGE.

HOWEVER, BECAUSE THEY WERE DEALING IN ADULTERED AND MISBRANDED DRUGS, ALL DEFENDANTS LACKED THE ASSURANCE OF SEALED,

STOCKED BOTTLES WITH ORIGINAL PACKAGING AND LABELING, LOT NUMBERS, EXPIRATION DATES AND OTHER REQUIRED DATA. THEY HAD NO ASSURANCE THAT THEY WERE NOT DEALING IN EXPIRED, STOLEN, MEXICAN MADE, CONTAMINATED OR OTHER DRUGS OTHERWISE HARMFUL TO THE CONSUMER. IN MOST CASES THEY WERE, IN FACT, DEALING IN SUCH PHARMACEUTICALS.

THE VICTIM IMPACT LIES IN THE FACT THAT IN ADDITION TO DEFRAUDING THE PHARMACEUTICAL MANUFACTURERS AND DRUG CONSUMING PUBLIC OF MONEY AND PROPERTY, PRODUCT INTEGRITY IS COMPROMISED BECAUSE SUCH ADULTERATED AND MISBRANDED DRUGS CANNOT BE RECALLED IN AN EMERGENCY AND THEIR POTENCY AND PURITY CANNOT BE ASSURED.

III. PUBLIC AND JUDICIAL RESPONSE

THIS INVESTIGATION AND RESULTING PROSECUTIONS HAVE RECEIVED WIDESPREAD PUBLIC ATTENTION. THE UNITED STATES ATTORNEY'S OFFICE, THE FBI OFFICE AND THE GEORGIA BOARD OF PHARMACY HAVE RECEIVED MANY CALLS FORM CITIZENS CONCERNED ABOUT THE SAFETY OF PRESCRIPTION DRUGS.

THE COURTS HAVE ALSO DONE THEIR JOB IN THESE CASES BY SENDING CERTAIN DEFENDANTS TO JAIL FOR THEIR TRANSGRESSIONS AGAINST SOCIETY. THESE JAIL SENTENCES SERVE THE ALL IMPORTANT FUNCTION OF DETERRENCE.

IN CLOSING, I WOULD LIKE TO READ TO YOU A BRIEF EXCERPT FROM THE SENTENCING HEARING IN ONE OF THESE PHARMONEY CASES BEFORE THE HONORABLE RICHARD C. FREEMAN OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA WHICH WE BELIEVE SUMMARIZES BOTH THE IMPORT AND NATURE OF THE PROBLEM ADDRESSED BY THIS INVESTIGATION AND PROSECUTIONS. IN SENTENCING

THE DEFENDANT IN THE CASE TO THREE YEARS IN PRISON, JUDGE FREEMAN STATED:

"I FORGOT ABOUT THE DIVERSION COUNT, BUT THAT DOES PRESENT SOME PROBLEMS BECAUSE THE TRIAL USUALLY ENDS THERE. IF THERE IS A RECALL AND YOU HAVE NOBODY, YOU DON'T KNOW WHO HAS THE DRUGS. YOU KNOW THEY WENT TO A HOSPITAL, BUT THE HOSPITAL LET THEM GO TO SOMEBODY ELSE, SO YOU DON'T KNOW WHERE THEY ARE.

IT IS A VERY SERIOUS THING, AND I DON'T THINK REALLY THAT THE PUBLIC UNDERSTANDS QUITE YET THE SERIOUSNESS OF WHAT HAS BEEN GOING ON. YOU OR SOMEBODY ELSE SAID IN A MEMO THAT I READ RECENTLY, MAYBE THIS WILL SHAKE UP THE PHARMACEUTICAL INDUSTRY AND THEY WILL DO SOME THINGS TO PREVENT THIS THING FROM HAPPENING IN THE FUTURE.

WE HAVE, FROM THE STANDPOINT OF DETERRENCE, WE HAVE NOT ONLY TO THINK OF MR. X. I DON'T BELIEVE MR. X WILL EVER BE BACK HERE AGAIN, HE WOULDN'T BE BACK HERE AGAIN ON A CHARGE SUCH AS THIS, I AGREE WITH YOU THERE.

BUT IT DOES NOT DO GOOD TO HAVE THE UNITED STATES ATTORNEY'S OFFICE WORKING WITH THE FEDERAL BUREAU OF INVESTIGATION ON A GREAT BIG NATIONWIDE PROGRAM TO GO OUT AND ROUND UP HUNDREDS OF PEOPLE WHO ARE DOING THIS SORT OF THING; AND THE PUBLIC GETS ALL AROUSED AND SAYS, THIS IS WONDERFUL,

SOMEBODY IS SPENDING OUR TAX DOLLARS WISELY, THEY ARE CATCHING THESE THIEVES AND THESE PEOPLE WHO ARE TAKING ADVANTAGE OF US; AND TO HAVE SOME JUDGE COME ALONG AND GIVE EVERYBODY PROBATION."

ON A PERSONAL NOTE, I WOULD LIKE TO EXPRESS MY DEEP APPRECIATION OF SPECIAL AGENTS CARL CHRISTIANSEN AND JOHN COFFEY OF THE FBI, SENIOR AGENT RICK ALLEN OF THE GEORGIA DRUGS AND NARCOTICS AGENCY WHO INITIALLY BROUGHT THE PHARMACEUTICAL DIVERSION PROBLEM TO OUR ATTENTION, AND ASSISTANT UNITED STATES ATTORNEY GALE MCKENZIE FOR THE VERY FINE JOB THEY DID IN OVERSEEING THE DAY TO DAY DETAILS OF THE INVESTIGATION AND PROSECUTIONS.

I WOULD ALSO LIKE TO COMMEND THE SUBCOMMITTEE FOR ITS WORK IN BRINGING TO THE ATTENTION OF THE AMERICAN PUBLIC THE SERIOUS PROBLEMS ASSOCIATED WITH DRUG DIVERSION.

THIS CONCLUDES MY PREPARED STATEMENT AND I WOULD NOW LIKE TO INTRODUCE TO THE SUBCOMMITTEE, MR. RICK ALLEN. MR. ALLEN IS A SENIOR AGENT WITH THE GEORGIA DRUGS AND NARCOTICS AGENCY.

AFTER MR. ALLEN'S PRESENTATION, I WOULD BE PLEASED TO ANSWER ANY QUESTIONS THE MEMBERS OF THE SUBCOMMITTEE MAY HAVE.

STATEMENT OF JEFFREY J. JAMAR, CHIEF, WHITE-COLLAR CRIMES SECTION, CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF INVESTIGATION, WASHINGTON, DC

Mr. JAMAR. Thank you, Mr. Chairman. I will address the fraudulent activity and theft that have given rise to a secondary market for legitimate medicines. Evidence in several FBI investigations has indicated this market is nationwide and its products are often adulterated, misbranded, or outdated. Generally, pharmaceuticals diverted into these markets are acquired when individuals make false representations to manufacturers and obtain products without cost, at discount, or at charitable prices. In many instances, manufacturers' sales representatives have ignored apparent fraudulent activity. These diverted medicines are then introduced into the retail market.

Drug diversion is not a recent phenomenon. Several individuals were indicted in 1982 as a result of one of our investigations into allegations they had fraudulently purchased medicines from various drug manufacturers at charitable prices. Using bogus charities, they wrote and telephoned manufacturers and requested a wide variety of products at 40 to 60 percent discount to aid the sick or poorer countries. These fraudulent representations resulted in approximately $10 million worth of drugs being donated or sold at charitable prices by drug manufacturers.

In reality, these pharmaceuticals were resold to United States wholesalers for distribution through retail drug and national outlets. Ten people were subsequently convicted. In August 1983, the owner of a small hospital pharmacy management firm was brought to the FBI by Richard Allen of the Georgia Drugs and Narcotics Agency, who is a participant in today's panel.

The owner advised he had been repeatedly approached by various individuals who requested that he order surplus pharmaceuticals for the seven hospital pharmacies he operated. One individual promised the owner $30,000 a month if he would place larger orders than needed by the nonprofit hospitals and sell the excess to him. What originally cost the owner 30 cents a tablet could bring him as much as 42 to 48 cents, that is, a 40 to 60 percent markup. Our cooperating witness could have made a significant amount of money with little or no effort by fraudulently using the "not for profit" or charitable status of the hospitals, but he was brought to work with the FBI by Rick Allen.

After a brief preliminary inquiry, it became apparent this type of activity was not only criminal but posed a danger to the health of the public who depend on these medicines. Due to the nature of the criminal activity, in January 1984, the FBI began an undercover operation. This investigation was given the code name "Pharmoney." Its purpose was to determine the scope of pharmaceutical diversion and to obtain evidence to convict those engaged in this criminal activity. "Pharmoney" focused on those who used their positions or businesses to purchase or receive pharmaceuticals at low or no cost and divert these products into the high-profit retail market. Once the undercover operation got under way, the operation focused on those who repackaged "outdated," "sample," or stolen products under less than sanitary conditions. These contami-

nated pharmaceuticals were then sold to local drug stores for ultimate delivery to the unsuspecting public.

An undercover agent working with Richard Allen began building a reputation as an affiliate of the company which initiated the complaint. In a relatively short period of time, the undercover operative became known as a trader in diverted pharmaceuticals. Once established, the operation began receiving unsolicited telephone calls from previously unknown individuals who expressed a strong desire to engage in the sale, trade, or exchange of diverted pharmaceuticals.

The diversion schemes took various forms. Among them we found: one, some pharmacists and purchasing agents submitting fraudulent orders in the name of legitimate institutions and reselling these goods; two, a fictitious clinic ordering pharmaceuticals; three, a clinic with only eight beds, claiming to have 200; four, a manufacturer's sales representative ordering more samples than were needed to distribute to medical and dental schools, and selling the excess for profit. Generally, the diverters were pharmacists, physicians, and past or present employees of pharmaceutical manufacturers, hospitals or clinics.

They included large national drug wholesalers, manufacturers' sales representatives, individuals who set up storage facilities solely for the diversion, and even a former industry executive who found diversion more lucrative than his previous employment. The undercover operation indicated that the demand for such diverted products far exceeded availability. Subjects constantly complained that they wanted larger quantities.

The statements of various subjects revealed numerous mechanisms which they used to obtain the diverted drugs and precautions they took to avoid detection. Some developed computer-generated profiles which, through a series of ordering procedures, allegedly maximized ordering capability, yet made orders appear realistic in both quantity and type of product. Others gained the assistance of the manufacturer's sales representative who could benefit from increased sales and income. At times, if questions were voiced regarding the amount of a certain pharmaceutical ordered, doctors and others vouched that the particular types of diseases requiring these medications were prevalent in the area.

The FBI's investigation identified several medical doctors who wrote to manufacturers requesting pharmaceuticals for their professional use and disbursement. These doctors asked for different "samples" each month and sold them.

The diverters removed the product from their original packages under less than sanitary conditions and eradicated the word "Sample" any way they could. They placed them in baggies and peddled them at back doors of neighborhood pharmacies. Outdated products which had been returned to the manufacturers' representatives for destruction were removed from their original packages and placed in any available container until they could be sold to the unsuspecting public, as you will see.

A California pharmacist said he regularly drove into Mexico, picked up cartons of products, and crossed the border into the United States with the products packed in the trunk of his car. Pharmoney also uncovered the theft of more than a quarter of a

million dollars worth of pharmaceuticals from a manufacturer's loading dock. This led to the charging of two sales representatives and a warehouse employee.

Statements from those who have plead guilty and who have assisted the FBI indicate the practice of diversion is widespread and has existed for many years. In fact, a former buyer for one national wholesaler stated that, when employed for that wholesaler, he was given the responsibility to seek out diverters and purchase as much of the diverted product as was available. He estimated purchasing over $27 million of diverted pharmaceuticals during a single year.

During the 18 months of the investigation, we gathered sufficient evidence to execute 13 search warrants in six States. An estimated $600,000 in diverted and adulterated pharmaceuticals were purchased and seized as part of this undercover operation. Over 80 convictions have been recorded to date as a result of this investigation.

I would like to express my personal gratitude for the efforts and support of the U.S. Attorney's Office of the Northern District of Georgia and the Georgia Drugs and Narcotics Agency—and particularly to Mr. Green—for bringing the investigation to a successful conclusion.

The various tablets, capsules, and liquids on display here are exactly as we found them in attics, basements, garages, and on pharmacy shelves. These, for the most part, are in unmarked bottles, bags, and jars. Some tablets had the word "Sample" removed with an electronic eraser, others a razor blade, and still others used Acetone, a toxic solvent.

Mr. Chairman, this concludes my statement.

Senator MATSUNAGA. Thank you very much, Mr. Jamar. Now, we will hear from Mr. Allen.

[The prepared written statement of Mr. Jamar follows:]

STATEMENT

OF

JEFFREY J. JAMAR

CHIEF

WHITE-COLLAR CRIMES SECTION

CRIMINAL INVESTIGATIVE DIVISION

FEDERAL BUREAU OF INVESTIGATION

WASHINGTON, D.C.

BEFORE THE

SUBCOMMITTEE ON INTERNATIONAL TRADE

SENATE FINANCE COMMITTEE

CONCERNING

DIVERSION OF PRESCRIPTION PHARMACEUTICALS

JUNE 15, 1987

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, I AM PLEASED TO BE HERE TO PRESENT THE VIEWS AND EXPERIENCE OF THE FEDERAL BUREAU OF INVESTIGATION REGARDING THE DIVERSION OF PHARMACEUTICALS.

I WILL ADDRESS THE FRAUDULENT ACTIVITY AND THEFT THAT HAVE GIVEN RISE TO A SECONDARY MARKET FOR LEGITIMATE MEDICINES. EVIDENCE IN SEVERAL FBI INVESTIGATIONS HAS INDICATED THIS MARKET IS NATIONWIDE AND ITS PRODUCTS ARE OFTEN ADULTERATED, MISBRANDED, OR OUTDATED. GENERALLY, PHARMACEUTICALS DIVERTED INTO THESE MARKETS ARE ACQUIRED WHEN INDIVIDUALS MAKE FALSE REPRESENTATIONS TO MANUFACTURERS AND OBTAIN PRODUCTS WITHOUT COST, AT DISCOUNT, OR AT CHARITABLE PRICES. IN MANY INSTANCES, MANUFACTURERS' SALES REPRESENTATIVES HAVE IGNORED APPARENT FRAUDULENT ACTIVITY. THESE DIVERTED MEDICINES ARE THEN INTRODUCED INTO THE RETAIL MARKET.

DRUG DIVERSION IS NOT A RECENT PHENOMENON. SEVERAL INDIVIDUALS WERE INDICTED IN 1982 AS A RESULT OF A PRIOR FBI INVESTIGATION INTO ALLEGATIONS THEY HAD FRAUDULENTLY PURCHASED MEDICINES FROM VARIOUS DRUG MANUFACTURERS AT CHARITABLE PRICES. USING BOGUS CHARITIES THEY WROTE AND TELEPHONED MANUFACTURERS AND REQUESTED A WIDE VARIETY OF PRODUCTS AT A 40 TO 60 PERCENT DISCOUNT TO AID THE SICK OF POORER COUNTRIES. THESE FRAUDULENT REPRESENTATIONS RESULTED IN APPROXIMATELY $10 MILLION WORTH OF DRUGS BEING DONATED OR SOLD AT CHARITABLE PRICES BY DRUG MANUFACTURERS. IN REALITY, THESE PHARMACEUTICALS WERE RE-SOLD TO UNITED STATES WHOLESALERS FOR DISTRIBUTION THROUGH RETAIL DRUG AND NATIONAL OUTLETS. TEN PEOPLE WERE SUBSEQUENTLY CONVICTED AS A RESULT OF THE INVESTIGATION.

IN AUGUST OF 1983, THE OWNER OF A SMALL HOSPITAL PHARMACY MANAGEMENT FIRM WAS BROUGHT TO THE FBI BY RICHARD ALLEN OF THE GEORGIA DRUGS AND NARCOTICS AGENCY, WHO IS A PARTICIPANT IN TODAY'S PANEL. THE OWNER ADVISED HE HAD BEEN REPEATEDLY APPROACHED BY VARIOUS INDIVIDUALS, WHO REQUESTED THAT HE ORDER SURPLUS PHARMACEUTICALS FOR THE SEVEN HOSPITAL PHARMACIES HE OPERATED. ONE INDIVIDUAL PROMISED THE OWNER $30,000 A MONTH IF HE WOULD PLACE LARGER ORDERS THAN NEEDED BY THE NON-PROFIT HOSPITALS AND SELL THE EXCESS TO HIM. WHAT ORIGINALLY COST THE OWNER 30 CENTS A TABLET COULD BRING HIM AS MUCH AS 42 TO 48 CENTS - THAT IS A 40 TO 60 PERCENT MARKUP. OUR COOPERATING WITNESS COULD HAVE MADE A SIGNIFICANT AMOUNT OF MONEY, WITH LITTLE OR NO EFFORT, BY FRAUDULENTLY USING THE "NOT FOR PROFIT" OR "CHARITABLE" STATUS OF THE HOSPITALS.

AFTER A BRIEF PRELIMINARY INQUIRY IT BECAME APPARENT THIS TYPE OF ACTIVITY WAS NOT ONLY CRIMINAL, BUT POSED A DANGER TO THE HEALTH OF THE PUBLIC WHO DEPEND UPON THESE MEDICINES. DUE TO THE NATURE OF THE CRIMINAL ACTIVITY, IN JANUARY, 1984, THE FBI'S ATLANTA OFFICE PRESENTED TO THE FBI'S CRIMINAL UNDERCOVER OPERATIONS REVIEW COMMITTEE A PROPOSAL REQUESTING AUTHORIZATION TO CONDUCT AN UNDERCOVER OPERATION TO ADDRESS PHARMACEUTICAL DIVERSION.

THIS INVESTIGATION WAS GIVEN THE CODE NAME "PHARMONEY". ITS PURPOSE WAS TO DETERMINE THE SCOPE OF PHARMACEUTICAL DIVERSION AND TO OBTAIN EVIDENCE TO CONVICT THOSE ENGAGED IN THIS CRIMINAL ACTIVITY. "PHARMONEY" FOCUSED ON THOSE WHO USED THEIR POSITIONS OR BUSINESSES TO PURCHASE OR RECEIVE

PHARMACEUTICALS AT LOW OR NO COST AND DIVERT THESE PRODUCTS INTO THE HIGH-PROFIT RETAIL MARKET. ONCE IT GOT UNDERWAY, THE OPERATION ALSO FOCUSED ON THOSE WHO REPACKAGED "OUTDATED", "SAMPLE", AND STOLEN PRODUCTS UNDER LESS THAN SANITARY CONDITIONS. THESE CONTAMINATED PHARMACEUTICALS WERE THEN SOLD TO LOCAL DRUG STORES FOR ULTIMATE DELIVERY TO THE UNSUSPECTING PUBLIC.

AN UNDERCOVER AGENT, WORKING WITH RICHARD ALLEN, BEGAN BUILDING A REPUTATION AS AN AFFILIATE OF THE COMPANY WHICH INITIATED THE COMPLAINT. IN A RELATIVELY SHORT PERIOD OF TIME, THE UNDERCOVER OPERATIVE BECAME KNOWN AS A TRADER IN DIVERTED PHARMACEUTICALS. ONCE ESTABLISHED, THE OPERATION BEGAN RECEIVING UNSOLICITED TELEPHONE CALLS FROM PREVIOUSLY UNKNOWN INDIVIDUALS WHO EXPRESSED A STRONG DESIRE TO ENGAGE IN THE SALE, TRADE, OR EXCHANGE OF DIVERTED PHARMACEUTICALS.

THE DIVERSION SCHEMES TOOK VARIOUS FORMS. AMONG THEM WE FOUND:

(1) SOME PHARMACISTS AND PURCHASING AGENTS SUBMITTING FRAUDULENT ORDERS IN THE NAME OF LEGITIMATE INSTITUTIONS AND RESELLING THESE GOODS;

(2) A FICTITIOUS CLINIC ORDERING PHARMACEUTICALS;

(3) A CLINIC WITH ONLY EIGHT BEDS CLAIMING TO HAVE 200, AND ORDERING ENOUGH PRODUCTS TO MEET THEIR INFLATED "NEEDS"; AND

(4) A MANUFACTURER'S SALES REPRESENTATIVE ORDERING MORE SAMPLES THAN WERE NEEDED TO DISTRIBUTE TO MEDICAL AND DENTAL SCHOOLS, AND SELLING THE EXCESS FOR PROFIT.

GENERALLY, THE DIVERTERS WERE PHARMACISTS, PHYSICIANS, AND PAST OR PRESENT EMPLOYEES OF PHARMACEUTICAL MANUFACTURERS, HOSPITALS, OR CLINICS. THEY INCLUDED LARGE NATIONAL DRUG WHOLESALERS, MANUFACTURERS' SALES REPRESENTATIVES, INDIVIDUALS WHO SET UP STORAGE FACILITIES SOLELY FOR THE DIVERSION, AND EVEN A FORMER INDUSTRY EXECUTIVE WHO FOUND DIVERSION MORE LUCRATIVE THAN HIS PREVIOUS EMPLOYMENT.

THE UNDERCOVER OPERATION INDICATED THAT THE DEMAND FOR SUCH DIVERTED PRODUCTS FAR EXCEEDED AVAILABILITY. SUBJECTS CONSTANTLY COMPLAINED THAT THEY WANTED LARGER QUANTITIES.

THE STATEMENTS OF VARIOUS SUBJECTS REVEALED NUMEROUS MECHANISMS WHICH THEY USED TO OBTAIN THE DIVERTED DRUGS AND PRECAUTIONS THEY TOOK TO AVOID DETECTION. SOME DEVELOPED COMPUTER GENERATED PROFILES, WHICH, THROUGH A SERIES OF ORDERING PROCEDURES, ALLEGEDLY MAXIMIZED ORDERING CAPABILITY YET MADE ORDERS APPEAR REALISTIC IN BOTH QUANTITY AND TYPE OF PRODUCT. OTHERS GAINED THE ASSISTANCE OF THE MANUFACTURER'S SALES REPRESENTATIVE, WHO COULD BENEFIT FROM INCREASED SALES INCOME AND SHARE IN THE DIVERTERS' PROFITS BY MERELY GOING ALONG WITH THE ORDERING TECHNIQUE. AT TIMES, IF QUESTIONS WERE VOICED REGARDING THE AMOUNT OF A CERTAIN PHARMACEUTICAL ORDERED, DOCTORS AND OTHERS VOUCHED THAT THE PARTICULAR TYPES OF DISEASES REQUIRING THOSE MEDICATIONS WERE PREVALENT IN THE AREA.

THE FBI'S INVESTIGATION IDENTIFIED SEVERAL MEDICAL DOCTORS WHO WROTE TO MANUFACTURERS REQUESTING PHARMACEUTICALS FOR THEIR PROFESSIONAL USE AND DISBURSEMENT. THESE DOCTORS ASKED FOR DIFFERENT "SAMPLES" EACH MONTH AND SOLD THEM TO THE DIVERTERS.

THE DIVERTERS REMOVED THE PRODUCT FROM THEIR ORIGINAL PACKAGES UNDER LESS THAN SANITARY CONDITIONS AND ERADICATED THE WORD "SAMPLE" ANY WAY THEY COULD. THE MEDICINES WERE PUT IN BAGGIES OR OTHER CONTAINERS AND PEDDLED TO THE "BACK DOOR" OF NEIGHBORHOOD PHARMACIES.

"OUTDATED" PRODUCTS, WHICH HAD BEEN RETURNED TO THE MANUFACTURERS' REPRESENTATIVES FOR DESTRUCTION, WERE REMOVED FROM THEIR ORIGINAL PACKAGES AND PLACED IN ANY AVAILABLE CONTAINER UNTIL THEY COULD BE SOLD TO THE UNSUSPECTING PUBLIC.

A CALIFORNIA PHARMACIST SAID HE REGULARLY DROVE INTO MEXICO, PICKED UP CARTONS OF PRODUCTS, AND CROSSED THE BORDER INTO THE UNITED STATES WITH THE PRODUCTS PACKED IN THE TRUNK OF HIS CAR. THESE PHARMACEUTICALS WERE SIMILAR TO UNITED STATES MANUFACTURED PRODUCTS BUT WERE PRODUCED AT PLANTS WHICH WERE NOT OPERATED UNDER STRICT UNITED STATES FOOD AND DRUG ADMINISTRATION STANDARDS. THIS PHARMACIST ADMITTED REPACKAGING AND DISTRIBUTING THESE DRUGS OF QUESTIONABLE PURITY ON A CASH BASIS ONLY.

PHARMONEY ALSO UNCOVERED THE THEFT OF MORE THAN A QUARTER OF A MILLION DOLLARS WORTH OF PHARMACEUTICALS FROM A MANUFACTURER'S LOADING DOCK. THIS LED TO THE CHARGING OF 2 SALES REPRESENTATIVES AND A WAREHOUSE EMPLOYEE. BUT WHAT IS SIGNIFICANT IS THE EASE WITH WHICH THESE GOODS FLOWED INTO THE SECONDARY OR DIVERSIONARY MARKET. THE TYPICAL EARMARKS OF STOLEN PROPERTY HAVE THE SAME CHARACTERISTICS AS DIVERTED PHARMACEUTICALS. THEY ARE: SIGNIFICANTLY LOWER THAN MARKET PRICE, NO DOCUMENTATION AND THE USE OF CASH IN COMPLETING THE TRANSACTIONS.

STATEMENTS FROM THOSE WHO HAVE PLEAD GUILTY AND WHO HAVE ASSISTED THE FBI, INDICATE THE PRACTICE OF DIVERSION IS WIDESPREAD AND HAS EXISTED FOR MANY YEARS. IN FACT, A FORMER BUYER FOR ONE NATIONAL WHOLESALER STATED THAT WHEN EMPLOYED FOR THAT WHOLESALER, HE WAS GIVEN THE RESPONSIBILITY TO SEEK OUT DIVERTERS AND PURCHASE AS MUCH OF THE DIVERTED PRODUCT AS WAS AVAILABLE. HE ESTIMATED PURCHASING OVER $27 MILLION OF DIVERTED PHARMACEUTICALS DURING A SINGLE YEAR.

DURING THE APPROXIMATELY 18 MONTHS OF INVESTIGATION, THE FBI WAS ABLE TO GATHER SUFFICIENT EVIDENCE TO EXECUTE 13 SEARCHES IN SIX STATES. AN ESTIMATED $600,000 IN DIVERTED AND ADULTERATED PHARMACEUTICALS WERE PURCHASED AND SEIZED AS PART OF THIS INVESTIGATION, INCLUDING HUNDREDS OF THOUSANDS OF TABLETS AND CAPSULES PACKAGED IN CONTAINERS VARYING FROM PLASTIC SANDWICH BAGS TO USED BREAD WRAPPERS. MOST OF THESE PACKAGES LACKED ANY IDENTIFYING DATA SUCH AS DRUG NAME, STRENGTH OR EXPIRATION DATE, AND, IN MANY INSTANCES WHEN SUCH DATA WAS ON THE CONTAINER, IT WAS ERRONEOUS. THESE DRUGS COMMONLY SAT IN ATTICS, MINI-WAREHOUSES, STORAGE SHEDS AND ON LOADING DOCKS EXTENDED PERIODS OF TIME WITH NO SANITARY OR ENVIRONMENTAL CONTROLS.

OVER 80 CONVICTIONS HAVE BEEN RECORDED TO-DATE AS A RESULT OF THIS INVESTIGATION.

I WOULD LIKE TO EXPRESS MY SINCERE GRATITUDE FOR THE EFFORTS AND SUPPORT OF UNITED STATES ATTORNEY'S OFFICE FOR THE NORTHERN DISTRICT OF GEORGIA AND THE GEORGIA DRUGS AND NARCOTICS AGENCY IN BRINGING THE INVESTIGATION TO A SUCCESSFUL CONCLUSION.

THE VARIOUS TABLETS, CAPSULES AND LIQUIDS ON DISPLAY HERE ARE EXACTLY AS WE FOUND THEM IN ATTICS, BASEMENTS, GARAGES, AND ON PHARMACY SHELVES. THESE, FOR THE MOST PART, ARE IN UNMARKED BOTTLES, BAGS AND JARS. SOME TABLETS HAD THE WORD "SAMPLE" REMOVED WITH AN ELECTRIC ERASER OTHERS A RAZOR BLADE, AND STILL OTHERS USED ACETONE, A TOXIC SOLVENT.

MR. CHAIRMAN, THAT CONCLUDES MY PREPARED STATEMENT.

STATEMENT OF RICHARD ALLEN, SENIOR AGENT, DRUGS AND NARCOTICS AGENCY, ATLANTA, GA

Mr. ALLEN. Thank you, Mr. Chairman. I am honored to be here this afternoon, and I would like to take a moment to thank Mr. Barr and the U.S. Attorney's Office in Atlanta, and especially the Federal Bureau of Investigation. The entire nation owes a debt of gratitude to these two organizations for an outstanding job in running these drug diversion investigations.

These cases were the first of their type ever undertaken successfully in this country, and the American public should be very proud of what has been accomplished in what we are talking about today. I come before you today with two points of view regarding the activity known as drug diversion. On the one hand, I am an investigator who has been exposed to drug diversion in some form or fashion almost daily for the past six years. On the other hand, I am a pharmacist who has personally viewed the reality of drug diversion and seen it to be at worst a collection of unbelievable horror stories and at best a disgusting breach of ethics.

Most of the time, I have found it hard to separate the investigator from the pharmacist when I have dealt with these cases. I have come to realize there is an automatic trust and high expectation in the integrity of the drugs manufactured by the companies in this country, a trust that is inbred in our health professionals as well as the American public.

It has always been and always should be unthinkable and unimaginable that anyone should mishandle, much less tamper with, or counterfeit any prescription drug in this country. I have found that today, after all the previous testimony in other hearings, all the criminal cases, all the evidence that has been presented, most people think diversion is over. They don't feel they will ever have to worry about getting a drug that is expired or counterfeit.

They think it is all over and done with. I have talked with pharmacy students whom I feel should be the most interested in what has been happening in their profession; and they think that drug diversion is something that is already over with, done, taken care of. And when I give these talks on diversion, they look at me as if I am some old war veteran telling a war story. This is something they shouldn't worry about. If this was true, then why are we all here today?

Because two months ago, a counterfeit drug containing no active ingredient except aspirin spread across this country almost overnight; because all of the so-called semihonest, decent diverters are out of the business. This left the market open for the hard-core, don't give a damn, money-hungry diverters; and as I speak, they are still out there, alive and well, making more money than ever before, so much more money that they are willing to take the risk of getting caught by the FBI and prosecutors such as Mr. Barr. And these are some of the reasons why we are here today.

Our agency began its investigation back in 1981. We began looking into reasons why doctors owned wholesale companies in Atlanta who tried to buy low-priced drugs from hospitals. Now, during these two years we learned what diversion was. We have the continued support of PMA members who helped us in the beginning

and taught us what diversion was about. They even sent us paperwork when they had problems. We found drugs moving from Oklahoma to Hawaii to California to Atlanta to Ohio, moving all over the country.

Now, again, we felt the drugs were coming through Atlanta at some point in time. Therefore, we began looking into it. For those two years my bosses, the Georgia Board of Pharmacy and my director, Bill Chism, were given updates on these cases. We had no legalities which we could prosecute on, and we were attempting to start proceedings as far as regulatory measures against these individuals.

And the U.S. Attorney's Office in Atlanta—Gale McKenzie—expressed an interest in prosecuting these cases. Gale was the first and only prosecutor in the country to take an interest in these cases; and I joined forces with Gale and FBI Special Agent Carl Christiansen, and we began the undercover operation known as "Pharmoney."

We went for almost two years in this operation. We started simply trying to find out where hospital drugs were being sold and purchased. Almost by accident, we ran into a market that existed to buy and sell drug samples.

Now, this was something I knew little about as a pharmacist because I only saw samples being traded for toothpaste by some of the sales representatives. And what you see before you is just one example of what we ran across that is what I consider a horror story.

The case has gone on beyond the two years of the undercover investigation. Mr. Christiansen left and went to a new assignment. We had Special Agent Coffey come in, and he and I and Ms. McKenzie continued with the investigation. And, it has gotten to this point today. We are seeing there are international incidents ongoing where millions of dollars worth of drugs that are supposedly shipped overseas, but actually they stay on the shores of this country; and most of the time either expired vitamins or bottled water are sent overseas in place of these drugs.

There are many instances of the drugs now being repackaged and hidden from the drug wholesalers or institutes. And where the diverters can't get their hands on drugs, so they turn to the medical device area—needles and syringes and such as that. They continue to divert; the market is still out there. It is still a problem to the health industry.

I could keep on giving examples, but I know I have a short time. My statement will give the other examples, but if I may, I will get up and give you some examples of what you have before you; and I will answer any questions you may have, sir.

Senator MATSUNAGA. Thank you very much, Mr. Allen.

[The prepared written statement of Mr. Allen follows:]

STATEMENT OF
C. RICHARD ALLEN, R.PH.
SENIOR AGENT, GEORGIA DRUGS & NARCOTICS AGENCY
BEFORE THE
SUBCOMMITTEE ON INTERNATIONAL TRADE
COMMITTEE ON FINANCE
UNITED STATES SENATE

JUNE 15, 1987

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE-

I AM HONORED TO BE HERE THIS AFTERNOON TO GIVE YOU AN OVERVIEW OF THE DRUG DIVERSION INVESTIGATIONS WHICH HAVE BEEN TAKING PLACE IN AND AROUND GEORGIA. I WOULD LIKE TO TAKE A MOMENT TO THANK MR. BARR, THE U.S. ATTORNEY'S OFFICE IN ATLANTA, AND ESPECIALLY THE FEDERAL BUREAU OF INVESTIGAITON. THE ENTIRE NATION OWES A DEBT OF GRATITUIDE TO THESE TWO ORGANIZATIONS FOR THE OUTSTANDING JOB DONE ON THESE DRUG DIVERSION INVESTIGATIONS, FOR THESE CASES WERE THE FIRST OF THEIR TYPE EVER SUCCESSFULLY UNDERTAKEN IN THIS COUNTRY. THE AMERICAN PUBLIC SHOULD BE VERY PROUD OF WHAT HAS BEEN ACCOMPLISHED RESULTING IN WHAT WILL BE DISCUSSED HERE TODAY.

I COME BEFORE YOU TODAY WITH TWO POINTS OF VIEW REGARDING THE FRAUDULENT ACTIVITY KNOWN AS DRUG DIVERISON. ON ONE HAND, I AM AN INVESTIGATOR, WHO HAS STUDIED AND BEEN EXPOSED TO DRUG DIVERISON, IN SOME FORM OR FASHION, ALMOST DAILY, FOR THE PAST SIX YEARS. ON THE OTHER HAND, I AM A PHARMACIST, WHO HAS PERSONALLY VIEWED THE REALITIES OF DRUG DIVERSION AND SEEN IT TO BE AT WORST, A COLLECTION OF UNBELIEVABLE, HORROR STORIES, AND A1 BEST, DISGUSTING, BREACHES OF ETHICS. AND, MOST OF THE TIME, I FIND IT HARD TO SEPARATE THE INVESTIGATOR FROM THE PHARMACIST WHEN I DEAL WITH DIVERSION CASES.

FOR, I HAVE COME TO REALIZE, THERE IS AN AUTOMATIC TRUST AND HIGH EXPECTATION IN THE INTEGRITY AND QUALITY OF THE DRUGS MANUFACTURED BY THE PHARMACEUTICAL COMPANIES IN THIS COUNTRY. A TRUST, THAT IS INBRED INTO OUR HEALTH PROFESSIONALS, AS WELL AS THE AMERICAN PUBLIC. IT ALWAYS HAS BEEN, AND ALWAYS SHOULD BE UNTHINKABLE-UNIMAGINABLE THAT ANYONE WOULD DARE MISHANDLE, MUCH LESS TAMPER WITH, OR COUNTERFEIT ANY PRESCRIPTION DRUG CONSUMED IN THIS COUNTRY.

AND TODAY, AFTER ALL THE PREVIOUS TESTIMONY, ALL THE CRIMINAL CASES AND ALL THE EVIDENCE THAT HAS BEEN PRESENTED, MOST PEOPLE THINK DIVERSION OF DRUGS IS OVER. THEY DON'T FEEL THEY WILL EVER HAVE TO WORRY ABOUT GETTING A DRUG THAT'S EXPIRED OR COUNTERFEIT; AFTER ALL THAT HAS BEEN DONE, SURELY, NO ONE IS ABOUT TO

DO SUCH THINGS AGAIN. I'VE EVEN TALKED WITH PHARMACY STUDENTS, WHO I FEEL SHOULD BE THE MOST INTERESTED IN WHAT HAS BEEN HAPPENING TO THEIR CHOSEN PROFESSION, AND I'VE FOUND THEY THINK DRUG DIVERSION IS OLD NEWS, PAST HISTORY - SOMETHING THAT DOESN'T HAPPEN ANYMORE. THEY ARE NOT CONCERNED WITH SUCH THINGS, AND THEY LOOK AT ME AS IF I'M AN OLD WAR VETERAN TELLING WAR STORIES.

IF THIS IS TRUE, THEN WHY ARE WE ALL HERE TODAY? BECAUSE, TWO MONTHS AGO, A COUNTERFEIT DRUG CONTAINING NO ACTIVE INGREDIENT EXCEPT ASPIRIN SPREAD ACROSS THE COUNTRY ALMOST OVERNIGHT. BECAUSE, ALL OF THE SO CALLED SEMI-HONEST, DECENT DIVERTERS ARE OUT OT THE BUSINESS, AND THIS LEFT THE MARKET WIDE OPEN FOR THE HARD-CORE, DON'T-GIVE-A-DAMN, MONEY HUNGRY DIVERTERS. AND, AS I SPEAK, THEY'RE STILL OUT THERE, ALIVE AND WELL, MAKING MORE MONEY THAN EVER BEFORE. SO MUCH MORE MONEY, THAT THEY ARE WILLING TO TAKE THE RISK OF GETTING CAUGHT BY THE FBI AND PROSECUTORS SUCH AS MR. BARR. THESE ARE SOME OF THE REASONS WHY WE ARE HERE TODAY.

TO BRING YOU UP TO TODAY'S POINT IN TIME, I'LL GIVE YOU A BROAD OVERVIEW OF HOW DIVERSION HAS OPERATED, GROWN AND CHANGED OVER THE PAST SIX YEARS, WHEN I WAS FIRST EXPOSED TO IT, AND REMEMBER, WHAT I KNOW IS BUT A SMALL PART OF HOW DIVERSION WORKS ACROSS THIS COUNTRY AND THE REST OF THE WORLD.

BACK IN 1981, MY AGENCY RECEIVED COMPLAINTS REGARDING AN ATLANTA DOCTOR WANTING TO BUY SURPLUS DRUGS FROM HOSPITALS. DRUGS AVAILABLE AT LOW PRICES. WE FOUND THIS DOCTOR OWNED A DRUG WHOLESALE COMPANY, AND, HE WAS RESELLING THESE HOSPITAL DRUGS TO NATIONAL DRUG CHAINS AND FULL LINE DRUG WHOLESALERS. LOOKING INTO THIS DOCTOR'S ACTIVITIES WAS THE BEGINNING OF A TWO YEAR SEARCH TO DETERMINE THE LEGALITY OF WHAT SEEMED LIKE AN UNETHICAL WAY TO BUY DRUGS.

DURING THESE TWO YEARS, WE HAD CONTINOUS SUPPORT FROM THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA) MEMBERS, WHO LITERALLY TOOK US BY THE HAND AND TAUGHT US THEIR BASIC UNDERSTANDING ABOUT HOW DIVERTERS OPERATED. THEY ENCOURAGED US TO LEARN ALL WE COULD, AND THEY ASSISTED US BY SENDING ANY KIND OF PAPERWORK CONCERNING DIVERSION, THAT HAD A TIE TO GEORGIA.

AND, WE LEARNED THE ASTONISHING NUMBER OF TIES THAT DID EXIST WITH GEORGIA. LINKS WERE FOUND WITH ALMOST EVERY OTHER STATE IN THE UNION. ONE PARTICULAR EXAMPLED WAS DRUGS BEING INVOICED AND SOLD TO A HOSPITAL IN HONOLULU, HAWAII, BY A DRUG WHOLESALER IN OKLAHOMA, BUT WITH THE DRUGS BEING SHIPPED TO A TRUCKING TERMINAL IN CALIFORNIA, USING THE NAME OF THE HONOLULU HOSPITAL, AND THEN BEING FORWARDED TO AN UNLICENSED DRUG WHOLESALER IN ATLANTA, AND THEN ON TO THEIR FINAL STOP IN OHIO AND NEW YORK.

FOR THOSE TWO YEARS, MY BOSSES, THE GEORGIA BOARD OF PHARMACY AND MY DIRECTOR, BILL CHISM, WERE BEING GIVEN UPDATES ON THE PROGRESS WE WERE MAKING. THE MORE WE LEARNED, THE MORE DETERMINED THE BOARD WAS TO GET TO THE BOTTOM OF THIS THING CALLED DIVERSION. I REMEMBER ONE BOARD MEMBER IN PARTICULAR, PETE MILLS, AN INDEPENDANT RETAIL PHARMACIST FROM SOUTHEAST GEORGIA. HE KEPT TELLING ME, HE FELT WE WERE ON TO SOMETHING MORE IMPORTANT AND A LOT BIGGER THAN ANY OF US REALIZED. (...AND, HOW PERCEPTIVE HE TURNED OUT TO BE).

THUS, IN 1983, WHEN WE WERE ASKED TO JOIN FORCES WITH THE FBI AND THE U.S. ATTORNEY'S OFFICE IN ATLANTA, THE BOARD ASSIGNED ME TO WORK EXCLUSIVELY ON THE DIVERSION INVESTIGATION, WHICH CAME TO BE KNOWN AS OPERATION "PHARMONEY".

AND, I STARTED WORKING WITH FBI SPECIAL AGENT CARL CHRISTIANSEN, WITHOUT WHOM, THE CASE NEVER WOULD HAVE BEEN AS SUCCESSFUL AS IT BECAME, AND WITH ASSISTANT U.S. ATTORNEY GALE McKENZIE, WHO WAS THE FIRST AND ONLY PROSECUTOR IN THE COUNTRY TO TAKE A CHANCE WITH THESE TYPE OF DIVERSION CASES.

WE CREATED A COMPANY, WHICH WAS SUPPOSEDLY PART OF A LEGITIMATE HOSPITAL PHARMACY MANAGEMENT BUSINESS. THIS GAVE US ACCESS TO LOW COST DRUGS, AVAILABLE THROUGH GEORGIA AND ALABAMA HOSPITALS. WE BEGAN BUYING LARGE QUANTITIES OF DRUGS AND RESELLING THEM TO A SINGEL DIVERTER. AND, OUR BUSINESS BEGAN TO GROW AS WORD SPREAD OF THE NEW KID IN THE DIVERSION WORLD. WITHIN A FEW MONTHS, WE WERE RECEIVING PHONE CALLS FROM ACROSS THE COUNTRY, WITH OFFERS TO BUY OUR DRUGS. THE DEMAND GREW TO A POINT, THAT IT FAR OUTDISTANCED ANY AMOUNT WE COULD EVER HAVE HOPED TO SUPPLY.

AND, ALMOST BY ACCIDENT, WE LEARNED OF A MARKET THAT EXISTED TO BUY AND SELL DRUG SAMPLES. THIS WAS SOMETHING I KNEW OF ONLY AS A SALES REP SOMETIMES TRADING A FEW SAMPLES TO A PHARMACIST FOR SOME TOOTHPASTE, OR REPLACING AN EXPIRED DRUG. BUT, AS YOU CAN SEE BEFORE YOU TODAY, THIS SAMPLE MARKET TURNED OUT TO BE ONE OF THOSE HORROR STORIES I MENTIONED. IF I MAY, IN A FEW MINUTES, I'LL SHOW THESE SAMPLES TO YOU AND EXPLAIN HOW THEY CAME TO BE HERE.

BUT, RIGHT NOW, LET ME CONTINUE ON TO TELL YOU OF SOME OF THE SCHEMES WE DISCOVERED DURING THE COURSE OF OUR INVESTIGATION. ONE, OF THE MOST IMPORTANT FINDINGS, WAS THE EXISTENCE OF A VAST, NATIONWIDE, UNDERGROUND NETWORK WHICH DISTRIBUTED THESE DRUG SAMPLES, ALONG WITH EVERY OTHER TYPE OF DRUG AVAILABLE THROUGH DIVERSION. THIS DISTRIBUTION NETWORK MOVES DRUGS BACK AND FORTH ACROSS THE COUNTRY, ALMOST OVERNIGHT. AND, IT HAS BEEN IN EXISTENCE FOR QUITE A NUMBER OF YEARS, WITHOUT ANYONE OUTSIDE THE NETWORK REALIZING IT EVEN EXISTED.

IT WAS BY BEING PART OF THE NETWORK, WE WERE ABLE TO LEARN HOW IT WORKED. WE WERE EVEN A PART OF IT FOR A LONG WHILE, WITHOUT OUR EVEN REALIZING IT OURSELVES. BECAUSE, THERE IS NO FORMAL STRUCTURE TO IT, NO LISTING, IN FACT WE WERE PROBABLY THE FIRST TO EVEN CALL IT A NEWTORK.

IT WAS THROUGH THIS NEWTORK, WE LEARNED OF A QUARTER-MILLION DOLLAR SHIPMENT OF ONE BRAND-NAME DRUG. WE FOUND 6,000 BOTTLES OF THE DRUG HAD GONE FROM A CHICAGO WAREHOUSE TO NEW MEXICO, THEN ON TO TEXAS, THEN KENTUCKY TO MISSISSIPPI BEFORE FINALLY STOPPING IN FLORIDA. AND, IT WAS ONLY AFTER WE CONTACTED THE MANUFACTURER ABOUT THIS DRUG, THAT THEY REALIZED THE 6,000 BOTTLES HAD BEEN STOLEN.

MOST IMPORTANTLY, WE FOUND THAT IT WAS THROUGH THIS NETWORK, THE VARIOUS COUNTERFEIT DRUGS WERE BEING INTRODUCED INTO THE UNITED STATES. THE DRUGS WERE SOLD BACK AND FORTH ACROSS THE COUNTRY AS JUST ANOTHER DIVERTED PRODUCT. IT APPEARS MOST OF THE DIVERTERS, THOUGHT THE DRUGS HAD COME FROM SOME NEW DIVERSION SOURCE, AND THE LOW SELLING PRICE SEEMED TO CONFIRM THIS THEORY. AND, THE MOST RECENT COUNTERFEIT DRUG, THE NAPROSYN, WAS DISTRIBUTED THROUGH THE MEMBERS OF THE NETWORK, WHICH CONTINUE TO REMAIN IN BUSINESS.

AND, THANKS TO THE PMA MEMBERS, WE UNCOVERED A GROUP OF PHYSICIANS, WHO WERE SUPPLYING DIVERTERS, WITH BRAND NAME STOCK BOTTLES OF DRUGS. THE PMA MEMBERS SENT A BUNDLE OF LETTERS, WHICH HAD BEEN SENT TO THEM BY SOME GEORGIA AND FLORIDA DOCTORS. EACH LETTER REQUESTED A FREE BOTTLE OF A SPECIFIC DRUG FROM A DIFFERENT MANUFACTURER. WE DISCOVERED AT LEAST 40 MANUFACTURERS HAD RECEIVED THESE LETTERS, AND ALMOST EVERY ONE OF THEM HAD SHIPPED THE FREE DRUGS REQUESTED. ADDITIONALLY, THESE LETTERS WERE BEING SENT ON A MONTHLY BASIS, FROM THE SAME DOCTORS, USING THE SAME WORDING, AND APPARENTLY USING THE SAME TYPEWRITER TO TYPE THE LETTERS.

WE EVENTUALLY FOUND ONE DOCTOR WORKING WITH A FORMER SALES REP, AND TOGETHER THEY WERE SENDING THESE LETTERS OUT THROUGH A GROUP OF DOCTORS THEY SOLICITED. THE REP GATHERED THE DRUGS UP FROM THE DIFFERENT DOCTORS' OFFICES AS THEY CAME IN, AND HE CARRIED THEM BACK TO THE OFFICE OF HIS DOCTOR PARTNER. ONCE THERE, THE DRUGS WERE INVENTORIED, PRICED , AND THEY WERE BOXED UP AND SHIPPED TO VARIOUS DIVERTER WHOLESALERS AROUND THE COUNTRY. THE GROUP OF DOCTORS WERE PAID 25% OF WHAT THEY TURNED OVER TO THE REP.

IN ADDITION, THE DOCTORS WERE ASKED TO REQEUST ALL THE SAMPLES THEY COULD GET FROM THEIR SALES REPS. THEY WERE PAID VARING PRICES FOR THEIR SAMPLES. THESE SAMPLES WERE ALSO BEING SOLD TO DIVERTERS AROUND THE COUNTRY. AND, LASTLY, THE REP HELPED SOME OF THE DOCTORS TO OPEN UP ACCOUNTS WITH VARIOUS MANUFACTURERS TO SERVICE WHAT WAS SUPPOSED TO BE ABORTION CLINICS BEING OPENED BY THE DOCTORS. IN FACT, THEY WERE CLINICS IN NAME ONLY, WITH UP TO $5,000 AND $10,000 WORTH OF DRUGS, AT LOW PRICES, BEING ORDERED EACH MONTH, AND THEN TURNED OVER TO THE REP FOR SALES TO DIVERTERS.

QUITE AN INGENIOUS OPERATION. WE INFILTRATED IT, AND EVENTUALLY TOOK ELEVEN DOCTORS TO COURT. WE EVEN MADE A PURCHASE OF $30,000 WORTH OF BIRTH CONTROL PILLS, SUPPOSEDLY STOLEN FROM THE LOADING DOCKS OF A MANUFACTURER IN PUERTO RICO. AND, THE PURCHASE WAS MADE FROM ONE OF THE DOCTORS, BESIDE AN INTERSTATE HIGHWAY IN SOUTH GEORGIA, IN THE MIDDLE OF THE NIGHT, WITH THE DOCTOR LAUGHING ABOUT THE DEAL FEELING LIKE SOME KIND OF COCAINE DEAL YOU WOULD SEE IN A MOVIE. THIS DOCTOR WAS SENTENCED TO FIVE YEARS IN PRISON, FOR MAIL FRAUD.

DURING THE TWO YEARS OF THE UNDERCOVER INVESTIGATION, OUR KNOWLEDGE OF DIVERSION GREW, ALMOST DOUBLED, ON A WEEKLY BASIS, IT GOT TO THE POINT, EVERY TIME WE LEARNED SOMETHING NEW, WE DIDN'T THINK THERE WAS ANYMORE TO LEARN, AND THEN WE WOULD BE STUNNED AGAIN BY WHAT WE FOUND THE NEXT WEEK.

NOW, IT HAS BEEN ALMOST TWO YEARS SINCE THE CASES WENT PUBLIC. CARL CHRISTIANSEN HAS MOVED ON TO A NEW ASSIGNMENT, AND NOW FBI SPECIAL AGENT JOHN COFFEY HAS ABLY JOINED OUR DRUG DIVERSION INVESTIGATION TEAM, AND WITHOUT MISSING A STEP, WE ARE STILL WORKING AND LEARNING EVERYDAY ABOUT WHAT'S NEW AND GOING ON IN THE WORLD OF DIVERSION. AND, WE SEEM TO BE CONSTANTLY TALKING WITH OTHER INVESTIGATORS FROM AROUND THE COUNTRY, TRYING TO HELP THEM LEARN ABOUT DIVERSION, AND ASSIST THEM WITH ANY POSSIBLE CASES THEY ARE BEGINNING TO WORK.

WE HAVE RECEIVED A TREMENDOUS AMOUNT OF INFORMATION REGARDING AMERICAN GOODS RETURNED: OR AMERICAN MANUFACTURED DRUGS BEING EXPORTED TO FOREIGN COUNTRIES, AND THEN ARE RETURNED TO THE U.S. MAINLAND FOR RESALE. THIS TYPE OF DIVERSION IS WITHOUT A DOUBT THE BIGGEST MONEY MAKER, AND INVOLVES THE LARGEST VOLUME OF DRUGS. AFTER PHARMONEY WENT PUBLIC, THIS TYPE OF DIVERSION STARTED TO INCREASE AT AN ALARMING RATE, MOSTLY DUE TO THE DECREASE IN AVAILABILITY OF THE HOSPITAL DRUGS. EXPORT WAS SLOWED DOWN SOMEWHAT BY THE DINGLE COMMITTEE REQUIRING FDA TO INSPECT AND RECORD ALL AMERICAN GOODS RETURING INTO THE COUNTRY, BUT PROBABLY 50% OF THE DRUGS SOLD FOR EXPORT NEVER LEFT THE COUNTRY IN THE FIRST PLACE.

IT HAS BEEN SHOWN WHERE SOME OF THE LARGEST WHOLESALERS IN THE COUNTRY, WERE PROVIDING MONEY UP FRONT TO DIVERTERS WHO COULD ARRANGE SALES BETWEEN THE MANUFACTURERS AND SUPPOSED FOREIGN BUYERS. THESE WERE 6 AND 7 FIGURE DEALS, WITH PROFITS RANGING UP INTO THE MILLIONS ON EACH DEAL.

THERE WERE MOUNTAINS OF PHONY SHIPPING DOCUMENTS PROVIDED TO THE MANUFACTURERS TO MAKE THEM BELIEVE THE DRUGS WERE ACTUALLY GOING TO PLACES LIKE LIBERIA, BOLIVIA AND HONG KONG. IN REALITY THESE DRUGS WERE ACTUALLY BEING SHIPPED TO WHOLESALER WAREHOUSES IN PLACES LIKE ATLANTA, NEW YORK, OR LOS ANGELES. MANY TIMES, WHEN A PHONY DOCUMENT COULDN'T BE ARRANGED, THE DIVERTERS WOULD INTERCEPT THE SHIPMENTS BEFORE THEY LEFT THE COUNTRY. THEY WOULD THEN SUBSTITUTE THINGS, LIKE BOTTLES OF

WATER, FOR THE DRUGS, IN ORDER TO SHIP THE SAME WEIGHT AS APPEARED ON THE ORIGINAL SHIPPING DOCUMENTS. THEN THEY RELEASE THE SHIPMENT TO BE EXPORTED TO WHEREVER IT WAS SUPPOSED TO GO.

THERE HAS EVEN BEEN A MARKET CREATED IN SALVAGE DRUGS. SOME DIVERTERS WERE EVEN BUYING ENOUGH DRUGS TO MAKE SALVAGE A FULL TIME, MONEY MAKING WHOLESALE BUSINESS.

SUPPOSEDLY, WHENEVER A MANUFACTURER OR WHOLESALER SHIPS DRUGS TO A CUSTOMER, THE SHIPPER IS AUTHORIZED TO RETURN THE SHIPMENT C.O.D. IF THE ORDER IS UNDELIVERABLE. IF A SHIPMENT IS LOST, THE MANUFACTURER NORMALLY INSURES THE DRUGS FOR A MINIMAL AMOUNT, LIKE $3 FOR A $60 RETAIL COST DRUG, AND THIS AMOUNT THE SHIPPER WILL PAY OFF THE LOST SHIPMENT.

OUR INVESTIGATION HAS SHOWN THAT-RARELY, IF EVER, ARE UNDELIVERABLE SHIPMENTS RETURNED TO THE MANUFACTURER. RATHER, THEY ARE CLAIMED AS LOST, AND THE SHIPPER PAYS THE INSURED RATE TO THE MANUFACTURER INSTEAD OF GOING TO THE TROUBLE OF RESHIPPING BACK TO THE MANUFACTURER. THE SHIPPER WILL THEN SELL THE DRUGS TO A SALVAGE YARD WHATEVER THEY PAID OUT IN INSURANCE. AND THIS HAS TURNED OUT TO BE HUGE QUANTITIES OF DRUGS THAT END UP AT SALVAGE COMPANIES.

IT IS AT THESE SALVAGE YARDS, WHERE AN ENTERPRISING DIVERTER WILL FIND DRUGS AT EXCEPTIONALLY GOOD BUYS. ONE MAJOR WHOLESALER, ROUTINELY PURCHASED SALVAGE DRUGS. IN 1984, WE FOUND THEY PURCHASED ONE HUGE SHIPMENT VALUED AT OVER A MILLION DOLLARS FOR LESS THAN $100,000. THE BIGGEST PROBLEM WITH THIS PARTICULAR PURCHASE WAS THAT THESE DRUGS HAD BEEN IN A FIRE AT ANOTHER WHOLESALE WAREHOUSE, AND THEY WERE SUPPOSED TO BE BURIED IN A LANDFILL.

BUT, THIS WHOLESALER SOMEHOW GOT IT'S HANDS ON THESE DRUGS. THEY THEN HAD THEIR EMPLOYEES SCRUB THE BLACKENED AND SOOTY BOTTLES WITH AJAX CLEANSER, AND THEN RUB COLGATE TOOTHPASTE ON THE LABELS TO WHITEN THEM UP SO THEY WOULD APPEAR NORMAL. THESE DRUGS WERE THEN SOLD TO UNSUSPECTING PHARMACIES AND WERE THEN DISPENSED TO UNSUSPECTING CONSUMERS. WHAT DRUGS THAT WEREN'T SOLD WERE BEING RETURNED TO THE VARIOUS MANUFACTURERS FOR CREDIT BY THE WHOLESALER, CLAIMING THESE DAMAGED DRUGS HAD BEEN PREVIOUSLY PURCHASED FROM THE MANUFACTURER BY THE WHOLESALER.

ANOTHER NEW WAY DIVERTED DRUGS ARE REACHING THE AMERICAN PUBLIC IS THROUGH MAIL ORDER PRESCRIPTION AND/OR DRUG REPACKAGING COMPANIES. WE HAVE FOUND, AGAIN SINCE PHARMONEY WENT PUBLIC, A DRAMATIC INCREASE IN THE NUMBER OF THESE COMPANIES GOING INTO BUSINESS---A SORT OF NEW GENERATION OF DIVERTERS.

THE MAIL ORDER PRESCRIPTION BUSINESS CAN ALMOST SPEAK FOR ITSELF, IN THAT THERE VIRTUALLY NO ONE OVERSEEING WHERE THESE COMPANIES BUY THEIR DRUGS EXCEPT OVERWORKED AND UNINTIATED STATE DRUG INSPECTORS. IT WOULD BE FAR TOO EASY FOR THESE PEOPLE TO SAY THEY ONLY BUY FROM LEGITIMATE SOURCES, AND THEN PRODUCE A HAND FULL OF INVOICES VERIFYING THIS. WHERE IN FACT, SINCE NOT ALL DRUGS ARE AVAILABLE THROUGH DIVERSION, THESE WOULD HAVE TO BE BOUGHT THROUGH ROUTINE SOURCES THUS, ONLY A FULL ACCOUNTING--WHICH IS NOT LIKELY TO BE DONE-NOR EVEN OFFERED—— WOULD BE THE ONLY WAY TO FIND DIVERTED MERCHANDISE.

THISAPPLIES TO DRUG REPACKAGERS AS WELL. THEY, REPACKAGERS, COME IN TWO BASIC TYPES, ONE REPACKS FULL-SIZE STOCK BOTTLES, TO BE USED BY THE DISCOUNT PHARMACY CHAINS. THE OTHER TYPE SUPPLIES THE DISPENSING PHYSICIANS WITH BOTTLES OF THE 12 OR 24 TABLET SIZE, FOR PHYSICIANS TO DISPENSE TO THEIR PATIENTS.

SUPPOSEDLY, REPACKS ARE FROM BULK SIZE CONTAINERS AVAILABLE FROM PHARMACEUTICAL MANUFACTURERS. BUT, IN REALITY, MOST MANUFACTURERS DO NOT SELL THEIR DRUGS IN BULK, NOR DO THEY SELL TO THE REPACKER.

IT SEEMS DRUG REPACKAGERS, ON A FEDERAL LEVEL, ARE REQUIRED ONLY TO REGISTER WITH THE FOOD & DRUG ADMINISTRATION FOR A REPACKING PERMIT. THEY SIMPLY HAVE TO FOLLOW FDA GUIDELINES FOR REPACKAGING, AND THEY ARE NOT INSPECTED BY THE FDA ON ANY ANNUAL BASIS TO VERIFY COMPLIANCE WITH THE GUIDELINES. FURTHER, DURING AN INSPECTION, THE FDA CANNOT REQUIRE THE PRODUCTION OF INVOICES SHOWING THE ORIGIN OF THE DRUGS. INSPECTIONS USUALLY CONSIST OF REVIEWING REPACKAGING LOGS TO CHECK FOR ANY EXPIRED DRUGS AND RECALLED LOT NUMBER.

IN ADDITION, NOT ALL OF THE STATES LICENSE DRUG REPACKAGERS OR DRUG WHOLESALERS. INCLUDED ARE STATES, WHICH HAVE NUMEROUS REPACKERS, SUCH AS ILLINOIS AND MISSOURI. THIS IN EFFECT MEANS, THESE REPACKAGERS, ARE RARELY VISITED BY THE FDA, BUT THEY ARE NEVER INSPECTED BY, NOR DO THEY ANSWER TO ANY STATE REGULATORY AGENCY. AND, IT SEEMS, WHEN STATES DO LICENSE REPACKERS, THE REGULATIONS VARY GREATLY FROM STATE TO STATE. PLUS, MANY STATES HAVE ONLY ONE, MAYBE TWO INSPECTORS, WHO ARE OVERWORKED AND DON'T HAVE THE TIME TO DO INDEPTH INSPECTIONS OF EVERY REPACKAGER. AND, WITH THE VARYING REGULATIONS, SOME STATES ALLOW UP TO FOUR AND FIVE DIFFERENT LOT NUMBERS AND EXPIRATION DATES, OF THE SAME DRUG, TO BE COMBINED UNDER ONE LOT NUMBER ASSIGNED BY THE REPACKAGER. OTHER STATES PROHIBIT SUCH ACTION. BUT, THESE MIXED LOT NUMBERS ARE STILL SOLD BY THE REPACKAGER IN ALL STATES.

ALL OF THIS COMES DOWN TO THE POINT, ANY TYPE OF DIVERTED DRUG AVAILABLE IN A QUESTIONABLE CONTAINER - EITHER BOTTLE OR BAGGIE, FOREIGN LABEL OR MANUFACTURED, HOSPITAL OR VETERINARIAN USE, TAMPERED WITH OR COUNTERFEIT, CAN BE

REPACKAGED AND NEVER BE DISCOVERED EXCEPT BY ACCIDENT.

AND WE'VE EVEN FOUND AN INCREASE IN THE NUMBERS OF NEEDLES, SYRINGES,---THE VARIOUS MEDICAL DEVICES - BEING DIVERTED. THE BOOMING HOME HEALTH CARE INDUSTRY IN THE U.S. CREATED A MARKETPLACE FOR INJECTIBLE DRUGS AND THIS LEAD TO A DRAMATIC INCREASE IN THE AMOUNT OF DIVERISON OF THESE PRODUCTS. WHEREAS THE DIVERTERS' GOLDEN RULE USE TO BE - ONLY ORAL DRUGS ARE DIVERTED, NEVER INJECTIBLES; BUT THIS IS NOT THE CASE ANY MORE.

ONE PHARMONEY SUBJECT, MARCHAR, HAD A BOOMING BUSINESS IN MEDICAL DEVICES, AND THESE PRODUCTS WERE DIVERTED FROM THE SAME TYPE SOURCES AS THEIR DRUGS. AND, EVEN THOUGH NOT SPECIFICALLY ADDRESSED IN DIVERSION LEGISLATION, THESE DIVERTED MEDICAL DEVICES CAN BE JUST AS MUCH OF A HAZARD TO THE AMERICAN PUBLIC AS ARE THE DIVERTED DRUGS.

SOME DRUG DIVERTERS ARE TURNING TO EXCLUSIVELY DIVERTING THESE DEVICES, IN AN EFFORT TO KEEP FROM COMING UNDER THE SCRUTINY OF DIVERSION INVESTIGATIONS. BUT, AGAIN AS WITH THE DRUGS, THE INTEGRITY OF THESE MEDICAL DEVICES CANNOT BE ASSURED ONCE THEY HAVE BEEN OUTSIDE THE NORMAL DISTRIBUTION NETWORK.

I COULD KEEP ON GIVING YOU EXAMPLE AFTER EXAMPLE OF THE SCHEMES WE'VE SEEN, BUT I HESITATE TO CONTINUE. IT WOULD TAKE A MONTH, JUST TO TELL YOU THE HIGHLIGHTS OF THE PAST SIX YEARS. I CAN ONLY HOPE, I HAVE BEEN ABLE TO EXPRESS TO YOU HOW IMPORTANT THIS LEGISLATION IS THAT YOU ARE NOW CONSIDERING. THE GEORGIA STATE BOARD OF PHARMACY AND THE GEORGIA DRUGS AND NARCOTICS AGENCY WISH FOR YOU TO KNOW THEY STAND BEHIND YOU 100% IN YOUR EFFORTS, AND THEY COMMEND YOU FOR WHAT YOU ARE ABOUT TO ACCOMPLISH.

FOR THE PRESCRIPTION DRUG MARKETING ACT OF 1987 IS A MONUMENTAL PIECE OF LEGISLATION. IN IT'S OWN WAY, IT WILL HAVE AS MUCH IMPACT ON THE PHARMACEUTICAL INDUSTRY AS THE CONTROLLED SUBSTANCES ACT OR THE HARRISON NARCOTIC LAW OF 1914.

MUCH AS A DRUG ADDICT CRYS OUT FOR SOMEONE TO RID HIM OF THE MONKEY ON HIS BACK, THE PRESENT DETERIORATED STATE OF THE PHARMACEUTICAL INDUSTRY'S DISTRIBTUTION SYSTEM, ALONG WITH THE AMERICAN PUBLIC, CRYS OUT FOR YOU TO RID THEM OF THE DIVERTERS ON THEIR BACK. THIS CONCLUDES MY FORMAL STATEMENT, AND NOW IF I MAY, I WOULD LIKE TO SHOW YOU SOME OF THE EXHIBITS WE BROUGHT WITH US TODAY. AFTER I HAVE FINISHED, I WOULD BE PLEASED TO ANSWER ANY OF THE SUBCOMMITTEE'S QUESTIONS.

Senator MATSUNAGA. Now, Mr. Barr, as an attorney, do you feel that the two bills before us would help in your work, in your investigation and prosecution, etcetera?

Mr. BARR. Without getting into endorsing, Mr. Chairman, particular legislation, they do provide tools that would be useful to a prosecutor in this area. Yes, sir.

Senator MATSUNAGA. Do you feel the same, Mr. Jamar?

Mr. JAMAR. Yes, sir.

Senator MATSUNAGA. And Mr. Allen?

Mr. ALLEN. Yes, sir.

Senator MATSUNAGA. I am glad to hear that. Mr. Allen, you are a pharmacist, so you know what you are dealing with; and the samples of confiscations we find before us, at least you would know what they are and what they are not. We laymen would not. How many of these samples before us, would you say, are ineffective drugs?

Mr. ALLEN. We really would not have a sure way to tell how many were ineffective because, as you can see, there is no indication of an expiration date on any of these drugs. We have no idea where they have been. We do know that some of the tablets up there that are thyroid were four years out of date before we even got our hands on them. They had been stored in an attic.

Senator MATSUNAGA. So, the American consumer would not know whether they are getting any effective drug or not?

Mr. ALLEN. No, sir. They would have no way of knowing, nor would retail pharmacists who would purchase the drugs have any idea or assurance of how current or how effective they were.

Senator MATSUNAGA. Of course, one of the sore spots, as I have heard, is that the hospitals and some of the nonprofit organizations feel that by the sale of the surpluses they are able to make a "go" of their organization, their institution, their hospital, etcetera. And by taking this privilege away, they would be forced to raise their prices on drugs. What would you say to that argument, Mr. Barr?

Mr. BARR. That really, I suppose, is not so much a question that a prosecutor should answer, Mr. Chairman. Of course, as the chair knows, all drug diversion is not illegal. What we are looking at here and what we have concentrated our efforts on from an investigative and prosecutorial standpoint—and the standpoint of the Northern District of Georgia—has been fraudulent, misleading diversion, which is the real heart of the problem.

It isn't simply the diversion itself. Diversion under regulated conditions with full knowledge of both parties and the ultimate consumer, as far as what they are getting, really is not something that we have been concerned with and may or may not be bad. It is the fraudulent practice, the unsanitary practice, the unregulated practice of diversion that is the heart of the matter and has given rise to the prosecutions across this country, Mr. Chairman.

Senator MATSUNAGA. Do you have anything to add, Mr. Jamar?

Mr. JAMAR. The priority in these investigations, as far as the FBI is concerned, is the threat to the health of the public, and our interest is based on that, and not the diversion itself.

Senator MATSUNAGA. Mr. Allen?

Mr. ALLEN. One of the things we forgot to mention is these drugs run through a network in this country, a network of diverters. The

counterfeit drugs that have been surfacing in the last three to four years went through this exact same network. The diverters felt that these drugs were merely another drug available at a low price. Most of them treated these drugs as not counterfeit. That is why these drugs moved so freely around this country, because of this network that exists of diversion—people who deal in drugs such as you see before you.

Senator MATSUNAGA. Ms. McKenzie, do you have any words of wisdom to add?

Ms. MCKENZIE. In response to your question: Do the sales of our hospitals create unfair competition to the honest retail pharmacist who can't get the drugs at that low price, and that is a violation of the Robinson-Patman Act.

Senator MATSUNAGA. Mr. Coffey, do you have anything that you feel ought to be said which perhaps has not been said?

Mr. COFFEY. I have nothing further to add, Mr. Chairman.

Senator MATSUNAGA. All right. Do you agree then that we have had a very fine panel of witnesses?

Mr. COFFEY. Yes, sir.

Senator MATSUNAGA. Thank you all. I appreciate your coming all the way from Georgia to help us in our effort to save the American consumer, as you say, millions or even billions of dollars.

Mr. BARR. Thank you, Mr. Chairman.

Senator MATSUNAGA. Our next panel of witnesses consists of pharmacists and their trade associations. I might point out the problem of drug diversion was first brought to my attention by my good friend, Bill Coombs of Long's Drug Store chain, a member of the National Association of Chain Drug Stores. Some of you may know him. It was Bill's argument and the arguments of my House colleague from Michigan, Congressman John Dingell, which convinced me to introduce The Prescription Drug Marketing Act. The pharmacists have really been at the forefront of the fight to protect consumers from diverted drugs which may be adulterated, mislabeled, or mishandled in shipping.

The panelists include Mr. John Rector, Counsel of the National Association of Retail Druggists; Mr. Ty Kelley, Vice President of the National Association of Chain Drug Stores; Mr. Ron Streck, Vice President of the National Wholesale Druggists Association; Mr. John Gans, the Immediate Past President of the American Association of Hospital Pharmacists; and Mr. John Schlegel, President of the American Pharmaceutical Association here in Washington, D.C.

Mr. Schlegel, maybe we can start with you.

STATEMENT OF JOHN F. SCHLEGEL, PRESIDENT, AMERICAN PHARMACEUTICAL ASSOCIATION, WASHINGTON, DC

Mr. SCHLEGEL. Thank you, Mr. Chairman. And in the interest of time, I will try to excerpt the high points of our testimony.

Senator MATSUNAGA. Yes, I would appreciate it if you would try to stay within the five minute limit. Thank you.

Mr. SCHLEGEL. Yes, sir. Mr. Chairman, as a pharmacist and as President of the American Pharmaceutical Association, I personally and organizationally am very interested in the work that your

subcommittee is doing, and we welcome the opportunity to work with you in dealing with the problems of the potential health and safety threats posed to the American consumers by prescription drug diversion and counterfeiting, as we so eloquently heard this morning.

I will address several key issues that we believe are critical to passage of effective legislation to help eliminate the drug diversion problem. Let me preface my comments by saying that we respectfully urge the subcommittee to include the compromise provisions included in H.R. 1207. Effective control over drug samples is an essential element for success in any attempt to reduce drug diversion.

For the past 40 years, the American Pharmaceutical Association has expressed its concern regarding the lack of controls over distribution, storage, packaging, and dispensing of prescription drug samples. We support the provisions of this legislation which would ban the sale, purchase, and trade of drug samples or drug sample coupons.

We also support provisions that would provide controls over the distributions of samples as set forth in the previously mentioned compromise to H.R. 1207. This would place strict controls on the manner in which drug samples may be distributed by mail, common carrier, or manufacturers' representatives. In each case, samples would be provided only in response to a specific written request from an authorized prescriber, utilizing an approved form.

In addition, the practitioner receiving the sample would have to issue a receipt to the manufacturer which would be kept on file for three years. We urge this subcommittee to incorporate language that would allow manufacturers' representatives under strict controls to distribute samples to physicians.

APhA also supports the legislative provisions such as those provided in your bill that would allow for flexibility by manufacturers in designing controlled drug distribution and sampling systems. APhA also supports features of the proposed legislation that would ban the sale, purchase, or trade of drugs donated or supplied at reduced prices to hospitals and other health care entities, including those covered under the provisions of Section 501(c)(3) of the Internal Revenue Code.

S. 368 recognizes the serious problems and health hazards caused by health care institutions which purchase prescription drugs in bulk at preferential institutional prices for the purpose of resaling these drugs for profit to pharmacies.

APhA supports the provision of the proposed legislation which would ban reimportation of export drug products by any person other than the original manufacturer of the product.

Provisions of the proposed legislation which would establish regulations and standards for operation of wholesale drug distributors are reasonable and importantly emphasize the necessity of proper storage and handling procedures and record keeping.

In summary, Mr. Chairman, APhA believes that this legislation would add important safeguards to the drug distribution system which is the envy of the world. APhA continues to treat this issue as extremely high on its priority; and if the legislation is enacted, we will be watching closely to evaluate whether it is achieving its

objectives. We stand ready to work with you, Mr. Chairman; and again, thank you for the opportunity to participate today.

Senator MATSUNAGA. Thank you very much, and we certainly appreciate your remaining within the allotted time, Mr. Schlegel. I think your experience in Washington helps. [Laughter.]

Senator MATSUNAGA. We will be happy now to hear from you, Mr. Streck.

[The prepared written statement of Mr. Schlegel follows:]

SUBMITTED BY
JOHN F. SCHLEGEL, PHARM.D.
PRESIDENT
AMERICAN PHARMACEUTICAL ASSOCIATION

Good morning Mr. Chairman. My name is Dr. John F. Schlegel. I am a pharmacist and President of the American Pharmaceutical Association (APhA). APhA is the national professional society of pharmacists representing the third largest health profession comprised of over 150,000 pharmacy practitioners, pharmaceutical scientists and students. Since its founding in 1852, APhA has been a leader in the professional and scientific advancement of pharmacy and in safeguarding the well-being of the individual patient.

We welcome the opportunity to work with the subcommittee in dealing with the problem of potential health and safety threats posed to American consumers by prescription drug diversion and counterfeiting. It is of grave concern to the entire profession of pharmacy. The subcommittee is to be commended for its achievements in addressing this issue and proposing S. 368, the "Prescription Drug Marketing Act of 1987."

Similar leadership on the part of the House of Representatives resulted last month in the passage of H.R. 1207, as amended. APhA supported H.R. 1207 and, like the House bill, we believe that S.368 contains the essential framework of effective drug diversion legislation.

In my comments here today, I will address several key issues that we believe are critical to passage of effective legislation to help eliminate the drug diversion problem. Let me preface my comments by saying that we respectfully urge the subcommittee to include the compromise provisions included in H.R. 1207 which I will describe in

my comments. APhA helped develop these provisions in order to expedite passage of this important legislation.

Effective control over drug samples is an essential element for success in any attempt to reduce drug diversion. For the past forty years APhA has expressed its concerns regarding the lack of controls over the distribution, storage, packaging and dispensing of prescription drug samples. We support the provisions of this legislation which would ban the sale, purchase and trade of drug samples or drug sample coupons. We also support provisions that would control the distribution of samples as set forth in the previously mentioned compromise to H.R. 1207. This would place strict controls on the manner in which drug samples may be distributed by mail, common carrier or manufacturers' representatives. In each of these cases, samples would be provided only in response to a specific written request from an authorized prescriber utilizing an approved form. In addition, the practitioner receiving the sample would have to issue a receipt to the manufacturer which would be kept on file for 3 years. We urge this subcommittee to incorporate language that would allow manufacturers' representatives under strict controls to distribute samples to physicians. Mail or common carrier should remain as the other acceptable methods.

APhA also supports legislative provisions such as those proposed in S.368 that would allow for flexibility by manufacturers in designing

controlled drug sample distribution systems. As an example of the importance of this provision, one national manufacturer has recently announced a pilot program for the distribution of samples for a particular prescription drug, whereby the physician provides the patient with a trial prescription order instead of drug samples. The pharmacist then dispenses the trial medication at no charge to the patient, and is reimbursed for the product and services by the manufacturer. Without the flexibility of this provision in S. 368, development of similarly innovative alternatives would not be possible.

APhA also supports features of the proposed legislation that would ban the sale, purchase or trade of drugs donated or supplied at reduced prices to hospitals and other health care entities, including those covered under provisions of section 501(c)(3) of the Internal Revenue Code. Provisions that would allow for sale within organizations which are under common control, or in true emergency circumstances, would be reasonable only as long as appropriate mechanisms are in place to prevent abuses through such redistribution. By proposing these provisions, the sponsors of S. 368 have recognized the serious problems and health hazards caused by health care institutions which purchase prescription drugs in bulk at preferential institutional prices for the purpose of reselling these drugs for profit to pharmacies. Such unethical schemes help fuel the diversion market and are an unfair form of competition to wholesalers and pharmacists who do not receive such deeply discounted preferential prices from manufacturers.

APhA supports the provision of the proposed legislation which would ban reimportation of exported drug products by any persons other than

the original manufacturer of the product, or in those emergency medical care situations so designated by the Secretary. We emphasize, however, the need for effective enforcement to minimize the potential for abuse of such a system.

Provisions of the proposed legislation which would establish regulations and standards for operation of wholesale drug distributors are reasonable and, importantly, emphasize the necessity of proper storage and handling procedures and record keeping. APhA believes that such provisions are in the best interest of all persons involved in the drug distribution system in this country.

In summary, APhA believes that this legislation would add important safeguards to a drug distribution system which is already the envy of the world. To maintain that excellence, it is essential that each of us involved in the system have the courage and wisdom to examine those portions of the system that do not perform as they should, and to be willing to work toward improvements that serve the public health. In this regard, APhA will continue to treat the distribution of drug samples as an issue of high priority and, if this legislation is enacted, we will be watching closely to evaluate whether it is achieving its objectives.

APhA stands ready to work with you, Mr. Chairman, and the subcommittee to ensure that effective legislation is enacted. Thank you for the opportunity to be here today and to share our views on this important topic.

STATEMENT OF RONALD J. STRECK, VICE PRESIDENT, NATIONAL WHOLESALE DRUGGISTS ASSOCIATION, ALEXANDRIA, VA

Mr. STRECK. Mr. Chairman, I only hope that I can remain within that green-lighted area as well. [Laughter.]

Mr. Chairman, the importance of the subject matter you are covering today—diversion of drug products—cannot be overemphasized. For decades the drug distribution system in this country has been considered one of the safest and most effective in the world. However, hearings before the House Energy and Commerce Subcommittee on Oversight and Investigations in the 99th Congress have shown that the distribution system, by which prescription drugs ultimately reach the consumer, is now being threatened by a drug diversion market.

You and the members of this subcommittee should be commended for holding this hearing; and Senator Matsunaga, your early leadership on this issue in the Senate gives us confidence that legislation will pass in the Senate in 1987.

We are certain that the House subcommittee's investigation has already helped the pharmaceutical industry become more—far more—aware, as a matter of fact, of the problems posed by diversion. In fact, the House-passed Prescription Drug Marketing Act of 1987, H.R. 1207, has this association's complete support. We are concerned that, if your bill, S. 368, passes in its present form, prescription drug products will not be distributed with efficiency. As a result, the cost of prescription drug products will rise significantly for consumers. We urge you to amend S. 368 by substituting the language found in H.R. 1207.

We believe that H.R. 1207, which has already passed in the House, has the full support of all major segments of the pharmaceutical industry at this time.

Just for a couple of minutes, if I could cover Section 6 of your bill? Section 6 of your bill, entitled Wholesale Distributors, would require all drug wholesale distributors of prescription drugs to provide each purchaser with a statement identifying the manufacturer of the drug, along with a complete audit trail of the drug product from the time it left the manufacturer's facility until the final sale by the wholesaler to the purchaser.

States would be required to license drug wholesalers in order for drug wholesalers to do business in the State, and the Secretary of HHS would be required to issue regulations establishing minimum standards, terms, and conditions for licensing of drug wholesale distributors. Dr. Bruce Sieker, our Director of Operations and Research, has reviewed that part of Section 6 which requires wholesale distributors to provide each customer a statement identifying the manufacturer of the drug and an audit trail of all sales transactions that occurred, beginning with the first sale of the product by the manufacturer.

I have included this memorandum, and I ask that it be included in the record of this hearing.

Senator MATSUNAGA. Without objection, it will be included in the record.

Mr. STRECK. He discusses the operation systems effects that Section 6 would have on prescription drug distribution. In his final ob-

servations, Dr. Sieker projects a threefold increase in average operating costs should Section 6 of S. 368 become law. A rather simple analogy can be used to explain the problems involved in complying with S. 368.

Performing a complete audit trail on every prescription drug product found in a wholesaler's inventory would be similar to performing a title search on real property. The purchaser of the real property and the purchaser of the prescription drug product receives from the title search company—or drug wholesaler—a complete trail of ownership of product or property. Now, consider the requirement that a title search or audit trail be completed on more than 50,000 parcels of property or product daily.

The increase in time, personnel, space, and computer records would be phenomenal. The electronic order entry program presently used by pharmacies 90 percent of the time would simply not be available. The increase in cost of administration at both pharmacies and wholesalers would be significantly higher and would certainly increase the cost of prescription drug products to the consumer.

If you look at Section 6 in H.R. 1207, the committee report accompanying H.R. 1207 states that the House Oversight Subcommittee's investigation found that most counterfeit and stolen, expired, or fraudulently obtained prescription drug products were handled by secondary suppliers who were not authorized to distribute a particular manufacturer's product.

As a result, Section 6 in H.R. 1207 does not require authorized distributors of record to provide complete audit trails to their customers. Rather, unauthorized distributors—those distributors who do not have an ongoing relationship with a manufacturer—would be required to certify in writing to drug wholesalers the source from which they obtained the drugs. Manufacturers would then be required to maintain for public review a current list of all authorized distributors of record.

We think that is far more efficient, far more sound, and would certainly benefit not only the consumer in providing the safety and effectiveness of all prescription drug products, but it would also guarantee that they would be able to obtain those prescription drug products at reasonable prices.

Thank you, Mr. Chairman.

Senator MATSUNAGA. You did bring it in time, too. [Laughter.]

Mr. Gans, we will be happy to hear from you now.

[The prepared written statement of Mr. Streck and memo from Dr. Bruce R. Siecker follows:]

STATEMENT OF

THE NATIONAL WHOLESALE DRUGGISTS' ASSOCIATION

Mr. Chairman and members of the Subcommittee, my name is Ronald J. Streck, and I am Vice President of Government Affairs for the National Wholesale Druggists' Association (NWDA). The importance of the subject matter you are covering today -- diversion of drug products -- can not be overemphasized. For decades the drug distribution system in this country has been considered one of the safest and most effective in the world. However, hearings before the House Energy and Commerce Subcommittee on Oversight and Investigations in the 99th Congress have shown that the distribution system by which prescription drug products ultimately reach the consumer is now being threatened by a drug diversion market.

You and the members of this Subcommittee should be commended for holding this hearing. Senator Matsunaga, your early leadership on this issue in the Senate gives us confidence that legislation will pass in the Senate in 1987. We are certain that the House Subcommittee's investigation has already helped the pharmaceutical industry become far more aware of the problems posed by diversion. In fact, the House passed "Prescription Drug Marketing Act of 1987" (H.R.1207) has this association's complete support.

We are concerned that if your bill, S.368, passes in its present form prescription drug products will not be distributed with efficiency. As a result, the cost of prescription drug products will rise significantly for consumers. We urge

you to amend S.368 by substituting the language found in H.R.1207. We believe that H.R.1207, which has already passed in the House, has the full support of all major segments of the pharmaceutical industry.

INTRODUCTION

The National Wholesale Druggists' Association (NWDA) is the national trade association of full-service drug wholesalers. Its membership of more than 310 distribution centers represents 86 U.S. drug wholesale corporations responsible for more than 95 percent of U.S. drug wholesale sales. In addition, more than 250 manufacturers of pharmaceuticals, over-the-counter drugs and health and beauty aids are affiliated with NWDA as associate members.

Annual surveys of prescription drug products sales in the United States prepared by the Pharmaceutical Manufacturers Association have shown that the percent of prescription drug products sold through wholesalers has increased annually from 51.4 percent in 1978 to 67.3 percent in 1985. The total sales of prescription drug products sold direct by manufacturers to retailers has decreased steadily from 22.8 percent in 1978 to 16 percent in 1985. Similarly manufacturers' sales of prescription drug products to private hospitals has steadily decreased from 16 percent in 1978 to 8.8 percent in 1985. The only other remaining category, "others", has also decreased from 9.8 percent in 1978 to 7.9 percent in 1985. The distribution of prescription drug products in the United States is being accomplished primarily by drug wholesalers.

Pharmacies now buy most of their prescription drug products from drug wholesalers for price and services. Drug wholesalers inventory and distribute only sealed stock bottles or other original packaging with complete labeling, lot number and expiration dates. They are required to meet all Drug Enforcement Administration (DEA) standards pertaining to records, reports and security.

NWDA member wholesalers go to great lengths to protect their customers and the public through proper regard for storage conditions, temperature, cleanliness and orderliness, inventory control, dating observation, returns handling, pilferage and theft prevention, frequency of delivery, local availability of supply in "as needed" quantities, and ability to perform drug product recalls.

SECTION 6 of S.368 SHOULD BE AMENDED

Section 6 of S.368 entitled, "WHOLESALE DISTRIBUTORS", would require all drug wholesale distributors of prescription drugs to provide each purchaser with a statement identifying the manufacturer of the drug along with a complete audit trail of the drug product from the time it left the manufacturer's facility until the final sale by the wholesaler to the purchaser. States would be required to license drug wholesalers in order for drug wholesalers to do business in the state, and, the Secretary of the Health and Human Services (HHS) would be required to issue regulations establishing minimum standards, terms, and conditions for licensing of drug wholesale distributors.

Dr. Bruce Siecker, director of operations and research for NWDA, has reviewed that part of Section 6 which requires wholesale distributors to provide each customer a statement identifying the manufacturer of the drug and an audit trail of all sales transactions that occurred beginning with the first sale of the product by the manufacturer. I have included his memorandum to me discussing the operations--systems effects that Section 6 would have on prescription drug distribution. In his final observations, Dr. Siecker projects a threefold increase in average operating costs should Section 6 of S.368 become law.

A rather simple analogy can be used to explain the problems

involved in complying with S.368. Performing a complete audit trail on every prescription drug product found in a wholesaler's inventory would be similar to performing a title search on real property. The purchaser of the real property and the purchaser of the prescription drug product receives from the title search company, or drug wholesaler, a complete trail of ownership of property or product. Now, consider the requirement that a title search or audit trail be completed on more than 57,000 parcels of property or product daily. The increase in time, personnel, space, and computer records would be phenomenal. The electronic order entry program presently used by pharmacies 90 percent of the time would simply not be available. The increase in cost of administration at both pharmacies and wholesalers would significantly increase the cost of prescription drug products to the consumers.

SECTION 6 of H.R.1207 SHOULD BE ENACTED

The Committee report accompanying H.R.1207 states that the House Oversight Subcommittee's investigation found that most counterfeit and stolen, expired or fraudulently obtained prescription drug products were handled by secondary suppliers who were no authorized to distribute a particular manufacturer's product. As a result, Section 6 in H.R.1207 does not require authorized distributors of record to provide complete audit trails to their customers. Rather, unauthorized distributors, those distributors who do not have an ongoing relationship with the manufacturer, are required to certify in writing to drug

wholesalers the source from which they obtained the drugs. Manufacturers are required to maintain, for public review, a current list of all authorized distributors of record.

Also, Section 6 of H.R. 1207 requires the Secretary of Health and Human Services to issue guidelines which will assure uniform standards covering the proper storage and handling of pharmaceuticals by wholesale distributors. We feel that the requirement that guidelines rather than regulations be issued by HHS will prevent regulatory duplication at the state and federal level. State agencies will establish licensure requirements for drug wholesale distributors in accordance with the HHS guidelines.

We believe that Section 6 of H.R. 1207 will protect consumers from counterfeit, stolen, expired and fraudulently obtained prescription drug products without severely increasing costs for distributing prescription drug products by legitimate wholesale distributors.

CONCLUSION

"The Prescription Drug Marketing Act of 1987" (H.R. 1207) controls counterfeit, stolen, expired and fraudulently obtained prescription drug products. This bill does not severely increase costs for the legitimate distribution of prescription drugs. The Senate bill, S. 368, controls counterfeit, stolen, expired and fraudulently obtained prescription products at a cost too great to consumers.

We support H.R. 1207 and ask you to substitute this language into S. 368.

Mr. Chairman, we stand ready to work with you and for you to assure appropriate legislation is passed to assure that American consumers can purchase prescription drugs with the certainty that the products they purchase are safe and effective.

MEMORANDUM

TO: Ronald J. Streck, VP Government Affairs

FROM: Bruce R. Siecker, Ph.D.

DATE: March 25, 1987

RE: Operations-Systems Effects of S.368

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The operations and systems effects of S.368 on NWDA drug wholesalers would be substantial and expensive. The effects are present no matter whether buying practices change or not. NWDA member wholesalers that are small, highly mechanized, highly systematized, or have a large number of inventory items would be affected most severely. These companies -- probably about half of our members -- would face serious and expensive problems in attempting to comply.

What follows is an operations and systems analysis of the effects this proposed law would have on NWDA wholesalers. Various ways of compliance are considered, based on a literal interpretation of the requirements. Wholesalers are considered to be full-service drug wholesalers that meet the NWDA definition of an active member.

OPERATION ISSUES

The typical NWDA wholesaler stocks 18,000 to 20,000 different items. Items are described as different stock-keeping units (SKUs) and represent definably different products, sizes, strengths, dosage form, etc. Wholesalers that service the hospital market have at minimum, 2,000 to 4,000 additional SKUs in stock. About 75 percent of the SKUs are prescription-only drugs, those addressed in S.368.

The range of SKUs is considerable; some members stock as few as 12,000 SKUs, some as high as 30,000 SKUs in a single location. To make this analysis easier to follow, it is assumed that the typical NWDA drug wholesaler has 19,000 SKUs in stock at any time.

Purchasing attempts to follow sales, but there is invariably a lag in the time between when a product is received into the warehouse and it is shipped. The practical significance of this is that the same product, bought at different times, is in the warehouse at the same time. Based on a requirement that the buying/selling history (including the dates) of each product for each sale must be recorded and conveyed to the buyer, the number of SKUs (for stocking and computer record purposes) exceeds the

nominal level by a factor of more than three times. This means keeping track of 57,000 items, because each purchase becomes a separate item (SKU) under S.368.

Wholesalers receive, breakdown (case packs), check-in, store, replenish, pick, pack, and ship products without ever marking individual packages. In fact, modern drug wholesale operations with its extremely low cost of operation depends critically on not having to do manual operations with individual items. Full cases are often sold as full cases, without ever being opened.

Being required to identify and track individual packages of each product by purchase source and purchase dates means one of two things operationally. Each purchase of each product on each date has to be stocked in a separate picking location or each package has to be labeled in some fashion.

Either approach means serious and expensive problems for most of NWDA members. Using separate picking locations immediately creates space, storage rack, and picking operations problems. I was unable to identify any drug wholesaler that could increase its number of picking locations threefold without expanding its warehouse (in some cases this is not possible because of physical limitations) and buying added storage and picking equipment, such as shelving, flow racks, carousels, conveyors, mechanized picking units, and so on.

A related problem has to do with picking lines. If inventory is spread over three times the space, picking lines will have to be extended. That means significant capital purchases. Also, there is a problem in trying to cover a longer picking line with the same number of pickers. Physical limitations and time-space requirements would slow down the picking operation, or drug wholesalers would have to hire additional people to maintain the same output. Either choice adds significant costs.

An extremely serious problem occurs for members who are not batch picking. With batch picking, a picker withdraws from storage the total number of packages needed to fill all orders from all customers received in one order cycle. Pickers pull the total quantity at one time; quantities for each order are then separated at the end of the picking line. For example, 100 customers may order today. Eighty may order ABC Cream, 4 oz., the total ordered is 150 dozen, divided among the 80 customers. Rather than pick ABC Cream, 4 0z., 80 times, the picker pulls 150 dozen at once. Specific order quantities are separated to assemble the orders at the end of the line.

A method to accomplish individual package identification – including which package was bought from which supplier on which date – is not evident at this time. Whether NWDA members could accomplish this and retain the operation efficiencies of batch picking is questionable.

The other approach – labeling each product - - poses equally serious hurdles. The key to modern wholesaling is moving large amounts of stock with minimal physical handling. Having to label each and every package of each and every SKU as it is received or stored, or restored after being returned from a customer (because additional audit trail information would have to be added) would mean a serious competitive

disadvantage, vis-a-vis, warehousing chain drug stores.

Maybe other approaches are plausible. Could products be labeled at the time of picking? The answer is no because it's impractical. Labeling at the time of picking implies the picker knows which products are which. That implies previous labeling or separate picking addresses, both very costly as discussed above. In addition, picking is only efficient, when the picker does not have to make decisions or think too long to pull the product. Such an approach would be impractical, given the type of people and training normally involved in picking in a drug wholesale warehouse.

Could price labels be used to solve the problem, meaning could members somehow code each price label they produce for customers to meet the requirement? This idea is probably the least feasible. Price labels are produced for each product for each pharmacy order. They are sent in bulk to be affixed by the buyer. They may be specific for each pharmacy, in terms of style or color. Trying to affix the price labels in the picking line implies that the picker knows which products are which, viz., which bottle of XYZ aspirin was purchased from which supplier on what date.

Again, there appear to be only two ways to do this -- create separate picking space for each product-supplier-date or labeling of some sort that would already be affixed to individual packages.

Attempting to affix a price sticker on the picking line with the pace and speed of a contemporary operation would not be feasible. It would slow the lines substantially or require more personnel. Its impracticality is worsened by the fact that not all customers purchase price sticker services, which means that there would have to be an alternative method to handle those situations.

Though not addressed here in detail, the challenges get much more complicated when returns are factored into the situation. Drugs returned from customers that are still in-date and in good condition are put back in stock for resale. If the separate storage-picking approach is taken, these products become different and therefore require another new picking slot. Overall, returns could add another one thousand SKUs to the equation. A package label approach still means creating new labels, because these products are now different in terms of S.368.

SYSTEMS ISSUES

Computer systems effects relate mostly to system storage capacity and file access time. Having to identify each purchase from each supplier on each date means every one of these would be a different record for computing purposes. Instead of keeping track of 19,000 SKUs, members' systems would have to record and retrieve 57,000 individual records. This increase occurs because, for computer purposes, each purchase is a separate record and would require its own space on the storage medium.

I am unable to identify any member who could triple -- or even double -- its computer records without having to invest in more disk capacity and faster processors to be able to access increased disk space in the same amount of time. There is still major variance among NWDA members in terms of their system's sophistication and capacity. Quite

clearly, smaller, less sophisticated members would be at a distinct disadvantage in trying to comply. Several probably could not and remain financially viable at this time.

A related problem is the need to produce much more detailed and, hence, longer invoices to explain the source and date of purchase of every package of every item in the order. Some items might require multiple invoice lines for explanation. Conservatively, invoice requirements would probably double. That means a slow down in production time or a need to upgrade the processor and printers to offset the time required to produce more detail. Both imply capital expenditures or loss of service levels and competitive position.

A seemingly minor but actually serious part of the proposed legislation are the words "before the sale" in Section 6, Section 503, Subsection B. If this literally means being able to tell the customer the source and date of purchase of each package before that customer purchases, the entire electronic order entry system is jeopardized. Presently, more than 90 percent of all orders are received via electronic one-way transmission. (Some members will not even accept telephoned orders anymore.) Electronic order entry is a one-way process -- the customer sends in the order without interaction with the wholesaler's receiving unit, which is a front-end processor that is not linked interactively to the mainframe in the evening when most orders are received.

Assuming "before the sale" means that a customer should be able to accept or reject each package of each SKU, I can find no feasible way to accomplish this today. Aside from the interactive requirement, the wholesaler's receiving processor has no way of knowing how many of a given item will be ordered in total for the order period. That means it has no way to tell the customer the necessary detail in any cases where there is product on hand from more than one supplier or purchases on different dates. If this literally means what is described above, electronic order entry and its ability to improve service ad cut costs may be history. Members will have to revert to telephone order -- taking or find a means to encumber specific packages, if each SKU as an order is recorded. That implies an ability for pickers to be able to know and identify which specific package of each SKU ordered belongs to which customer. A solution to this possibility is not readily evident.

FINAL OBSERVATIONS

NWDA members have developed highly mechanized and highly automated means for moving large quantities of tens of thousands of items to their customers. That ability hinges critically on their ability to minimize manual handling and detailing identification of each package. In 1985, NWDA members serviced the industry at an average operating cost of only 6.17 percent. The requirements implied in this bill can be expected to increase costs substantially, no matter what approach members take to comply, and set order-entry automation back to what was evident in the 1960's, when operating expenses averaged 16 to 18 percent.

STATEMENT OF JOHN A. GANS, PHARM.D., IMMEDIATE PAST PRESIDENT, AMERICAN SOCIETY OF HOSPITAL PHARMICISTS, BETHESDA, MD

Mr. GANS. Thank you, Mr. Chairman. I will try to make it three in a row. [Laughter.]

The problems associated with the practice of drug diversion are ones in which all those involved in the drug distribution system must share some of the blame.

Whether the issue is sampling, reimportation, counterfeiting, or bulk resale or purchase of drug products—manufacturers, wholesalers, hospital pharmacists, community pharmacists, and chain drug stores—must all assume responsibility for tolerating, permitting, and, in some cases, even actively participating in situations that may compromise the public health.

Over the last several years, ASHP has worked to find effective solutions to the problem at hand. We therefore appreciate the opportunity to participate in the subcommittee's own efforts. We would like to address a number of specific issues relating to the problem of drug diversion.

Without a doubt, the bulk resale of drug products by hospitals and others to redistributors has been an important part of the gray market drug problem that exists today. We believe that the penalties included in S. 368 and H.R. 1207 represent a major step in providing a sufficient deterrent to this practice. ASHP's concern about this practice is long standing. In 1983 in our journal, "The American Journal of Hospital Pharmacy," we published an editorial about the legal risks of bulk resale and published an opinion in that same journal. In addition, ASHP became the first pharmacy organization to formally advocate legislation designed to clearly prohibit the bulk resale of drugs by pharmacists.

However, those who continue to point to hospital purchases as the root of the cause of drug diversion do not get to the heart of the problem at hand. Even as some have claimed, the elimination or curtailment of the benefits of Section 13(c) of the Robinson-Patman Act was enacted into law, it would only be partially effective. For example, 13(c) would not affect sales by nonprofits of goods purchased under the traditional Robinson-Patman discounts. Likewise, sales by proprietary institutions whose purchases are not covered by the Section 13(c) exemption could continue as a major source of drug diverters.

Indeed, of the 34 hospitals named in a major investigation involving hospital and nursing home resales, only four were in not-for-profit institutions. Thus, to maintain that the noble objectives of the nonprofit institution act must be repealed in order to prevent drug diversion is a position that has been fully discredited.

In our view, Mr. Chairman, the provisions in S. 368 and H.R. 1207 would deal forcibly, effectively, and unequivocally with the problems at hand. However, we are pleased that neither bill would disturb the public policy embodied in the Nonprofits Institution Act.

On the issue of sampling, one of the major disturbing elements of drug diversion has been a disclosure of numerous abuses and practices associated with manufacturers' sampling, that we have heard

already this morning. For 10 years, ASHP has been opposed to the continuation of sampling in this country.

We have four parts to that particular policy. Number one, we believe that sampling serves no real health care need for the American consumer. Number two, the lack of control of the distribution of samples creates a major health risk through improper storage and major adulteration, also the legal accountability of the product itself.

Number three, the use of samples increases the costs of drug products. Number four, samples provide access to prescription drugs by unauthorized, untrained personnel. And number five, samples are rarely provided in childproof containers. In short, while ASHP recognizes the complexities involved in other segments of the drug distribution scandal, we believe that the issue of sampling offers Congress a unique opportunity to eradicate at least this aspect of the problem. It is clear that any purported benefits of sampling are far outweighed by the public interest in eliminating the risks involved with continuation of this practice.

While the proposals regarding sampling in S. 368 and H.R. 1207 will improve the current situation, ASHP recommends that Congress consider prohibiting the distribution of sampling all together of prescription drug products.

Mr. Chairman, you have heard this morning from the investigative team; and the issue before us, as I see it, is public erosion of confidence in the drug products they are taking. We have a major problem right now in getting people to take their drugs properly; and as long as we allow this condition to exist in this country, we are going to have more erosion of that confidence that a drug product is what it is intended to be.

We appreciate the opportunity to be here this afternoon. Thank you.

Senator MATSUNAGA. Thank you very much. You also made it in time. The bell didn't ring on you. [Laughter.]

As I understand it, instead of Mr. Rector, we have Mr. Calvin Anthony of the National Association of Retail Druggists from Alexandria, Virginia. We will be happy to hear from you, Mr. Anthony.

[The prepared written statement of Mr. Gans follows:]

STATEMENT

OF THE

AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

The American Society of Hospital Pharmacists (ASHP) is the national professional society of pharmacists practicing in hospitals and other organized health-care settings; membership in ASHP is approximately 21,000. Our members, as pharmacists have a special ethical and legal responsibility to ensure the safety and efficacy of drugs dispensed to our patients. Many of those basic responsibilities are set forth in various federal statutes and regulations, such as the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., Controlled Substances Act, 21 U.S.C. 801 et seq., and Medicare Conditions of Participation 42 C.F.R 405.1027, as well as in state laws governing the practice of pharmacy. ASHP and its members have also moved far beyond these basic standards and have been at the forefront of the fight to protect and improve the quality of the public health by providing innovative, comprehensive and cost-effective pharmaceutical services.

The commitment of ASHP and institutional pharmacy to improving professional practice in the public interest is well documented. ASHP has fostered "innovative" pharmaceutical services that have subsequently become the norm in organized health-care settings. Some of those standards, contained in more than 50 separate documents, are published in "Practice Standards of the American Society of Hospital Pharmacists, the only work of its kind in the profession. Our standard have served as a beacon for the rest of the profession as it seeks to upgrade professional practice. Many of the ASHP standards have been incorporated into various state

laws and regulations and adopted by such quality-assurance bodies as the Joint Commission on Accreditation of Hospitals (ASHP is currently working with JCAH to develop standards for home health care services). Such improvements as the unit dose drug distribution system,[1] centralized intravenous admixture services,[2] clinical pharmacy services,[3] and the hospital formulary system[4] were all conceived by hospital pharmacists and implemented through the standard-setting activities of ASHP and the efforts of our members. With this record in mind, we wish to assure the Subcommittee of ASHP's willingness,

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[1]ASHP Statement on Unit Dose Drug Distribution System (1985). The unit dose drug distribution system is a pharmacy-coordinated system of medication distribution in which medication orders are reviewed by pharmacists, filled in ready-to-administer form, and sent to patient-care areas when the medication is to be administered. This system of drug distribution and control reduces medication errors and overall costs. See Comptroller General Report, "Potentially Dangerous Drugs Missing in V.A. Hospital--A Different Pharmacy System Need" 1975).

[2]A centralized intravenous admixture service, an extension of the unit dose drug distribution system, is one in which all intravenous fluids are prepared in the pharmacy where proper compounding and sterility can be assured. See Recommendations of the National Coordinating Council on Large Volume Parenterals.

[3]ASHP Statement on Clinical Functions in [illegible]titutional Pharmacy Practice (1978). Clinical pharmacy serv[illegible]s provide a pharmacist's unique expertise on drugs and their actions to physicians, nurses, and patients through patient education, drug therapy monitoring and counseling, and drug information services.

[4]ASHP Statement on the Formulary System (1983). A formulary system is a method whereby an institution's medical staff, working through its pharmacy service, evaluates and selects from among numerous drug products only those most useful in patient care to assure quality and to control cost. A modern formulary system may involve selecting generic or therapeutic equivalents.

desire, and sense of obligation to help resolve some very real compromises to the integrity of the nation's drug supply; on behalf of our members, we also assure you of our collective desire to help eliminate this problem.

Mr. Chairman, the problems associated with the practice of drug diversion are ones in which all those involved in the drug distribution system must share some blame. Whether the issue is sampling, reimportation, counterfeiting, or bulk resale and purchase of drug products, manufacturers, wholesalers, community pharmacies, and chain drugstores must all assume some responsibility for tolerating, permitting, and, in some cases, even actively participating in situations that may compromise the public health. Hospitals of course, cannot escape their own responsibility; some hospitals--we believe a very small minority--have been a substantial source of drug products entering into the "gray market." S. 368 and H.R. 1207 appropriately do not focus punitively on any one group or deal with issues that do not fully address the subject of these hearings. Rather, both bills effectively provide a resolution of the problem that is simple, effective, and comprehensive and looks to each sector of the prescription drug distribution system to meet its responsibility in resolving the dilemma.

In our view, the most unsettling aspect of the evidence generated by the hearings conducted by the House Subcommittee on Oversight

of the Energy and Commerce Committee is the unavoidable conclusion that we face a serious health problem: the movement of drug products outside normal channels of distribution (a "gray market"), which inhibits tracking and identification of products in case of recall and which facilitates market entry of counterfeit, adulterated and misbranded products and their dispensing to consumers. Over the last several years, ASHP has worked to find effective solutions to the problem at hand. We, therefore, appreciate the opportunity to participate in the Subcommittee's own efforts.

We would now like to address a number of specific issues relating to the problem of drug diversion.

Bulk Resale of Drug Products

Without a doubt, bulk resale of drug products by hospitals and others to redistributors has been an important part of the "gray market" problem. While our impression is that this activity is confined to a relatively few institutions--and that participation in these schemes is largely an institutional and not an individual decision-precise figures are far less important than the fact that <u>any</u> "gray market" bulk resale compromises the integrity of the drug supply. In our view, it is a nefarious practice that, though currently inhibited by law should be explicitly prohibited by legislation containing serious criminal and civil sanctions applied to those who engage in bulk resale of drug products <u>as well as</u> those who purchase or deal in diverted drug products.

We believe that the penalties included in S. 368 and H.R. 1207 represent a major step in providing a sufficient deterrent to this practice. ASHP's concern about this practice is longstanding. In 1983, our legal department outlined the considerable legal risks of bulk resale and published this opinion in the American Journal of Hospital Pharmacy for all our members to read; we believe that this was the first public statement on the issue from the profession. We have regularly advised our members of our substantial concerns about this practice and, in 1985, we discussed our serious concerns about the problem with the American Hospital Association. In June of 1985, our House of Delegates adopted the following policy relative to bulk resale of drug products:

> To support legislation that would specifically prohibit bulk resale of drugs by pharmacies except for any (1) sales otherwise permitted by law to affiliated corporations in furtherance of a planned, integrated approach to delivery of health care within a health care corporate structure and (2) sales by bona fide group purchasing arrangements to members.

Finally, in August of 1985 the American Journal of Hospital Pharmacy carried an editorial that roundly condemned the participation of pharmacists in bulk resale.

Current statutes, while addressing this problem only indirectly, do indicate the serious legal risks attendant to "gray market" transactions. For example, ASHP believes that the tax-exempt status of nonprofit entities purchasing large quantities of drugs for resale could be denied if the scope and extent of sales met Internal Revenue Service criteria for revocation of tax-exempt status. Carle Foundation v. Internal Revenue Service. Sections of the Racketeer Influenced Organized Crime Act of 1970, 18 U.S.C. 1961 et seq. (RICO) might also be a potent tool to criminally sanction the entire scope of "gray market" activity, if accompanied by fraud or misrepresentation; RICO might serve as a particularly effective tool for all pharmacy to privately police its activities relating to "gray market" drugs through civil litigation. The Criminal Fine Enforcement Act of 1984, Pub.L. 98-596, 98 Stat. 3134, et seq., also imposes very high fines--up to $250,000 for individuals and $500,000 for corporations--for violations of those sections of the Federal Food, Drug and Cosmetic Act concerning trading, holding, or dealing in counterfeits or adulterated or misbranded drugs.

Obviously, the strongest statutory prohibition against bulk resales is in the Nonprofit Institutions Act itself, 15 U.S.C. 13c. Section 13c of the Robinson-Patman Act, 15 U.S.C. 13, limits drugs purchased at special prices by nonprofit institutions to the institutions' "own use." Precedents under Section 13c have defined the permissible scope of the phrase

"own use," and, in our view, even the most liberal reading of those cases would prohibit "gray market" sales. See, e.g., Portland Retail Druggists Association v. Abbott Laboratories, 425 U.S. 1 (1976); Jefferson County Pharmaceutical Association v. University of Alabama Hospital and Clinics, 460 U.S. 150 (1983); De Modena et al. v. Kaiser-Permanente Foundation, 743 F.2d 1388 (1984), cert. denied, 53 U.S.L.W. 3587 (U.S., February 19, 1985). Hospitals certainly can have no objection to "playing by the rules" and so should comply with the limitations and benefits of Section 13c and if increased vigilance by FTC is needed to enforce the law, ASHP has long believed that the agency should be given unequivocal direction and funding to do so.

However, those who continue to point to hospital purchases as the root cause of drug diversion do not get to the heart of the problem at hand. Even if, as some have claimed, elimination or curtailment of the benefits of Section 13c were enacted into law it would be only partially effective. For example, Section 13c would not affect sales by nonprofits of goods purchased under traditional Robinson-Patman discounts. Likewise, sales by proprietary institutions whose purchases are not covered by the Section 13c exemption could continue as a major source for drug diverters. Indeed, of the 34 hospitals named in a major investigation involving hospital and nursing home resales, only

four were not-for-profit institutions. Thus, to maintain that the noble objectives of the Non-profit Institutions Act must be repealed in order to prevent drug diversion is a position that has been fully discredited. Finally, repeal or modification of Section 13c would not stop the public health problem arising from samples and counterfeits finding their way into the "gray market," nor would it deter purchases of "gray market" drug products.

We, therefore, commend the Subcommittee for considering legislation that fairly and comprehensively addresses the problem by dealing effectively and strongly with all parties who compromise our nation's health care by dealing in "gray market" drug products.

In our view, Mr. Chairman, the provisions in S. 368 and H.R. 1207 would deal forcefully, effectively, and unequivocally with the problems at hand.

State Law Enforcement

Still, ASHP believes that reliance on federal legislation alone is not sufficient in dealing with the problem of drug diversion. One of the most effective means to police the "gray market" is through local enforcement of state licensing statutes. Virtually all state practice acts permit professional licenses to be revoked for "unprofessional conduct." See National Association of Boards of Pharmacy Survey of Law, 1984. Unfortunately, the lack of clarity about the legality of bulk resales and purchases appears to have precluded an aggressive policing action at the local level.

We urge state regulatory boards to take strong action against physicians, wholesalers, pharmacists, and pharmacies dealing in "gray market" drugs. We believe that these hearings and any future legislative deliberations may provide the impetus for more vigorous local enforcement of licensure laws. It is important to note that, as the Committee Report documented, some centralized purchasing agents are not pharmacists; we therefore note the need to act against both pharmacists and pharmacies dealing in the "gray market."

Sampling

Perhaps one of the more disturbing elements of drug diversion has been the disclosure of numerous abusive practices associated with manufacturers' sampling. As numerous investigations have detailed, large quantities of drug products, originally intended to be distributed as samples, have surfaced in commercial distribution channels and have been illegally resold to consumers as bona fide products. The methods by which these samples are "transformed," the health risks associated with their entry into distribution channels, and the various laws violated by such activity are now legendary. Although this component of the drug diversion dilemma has shocked many, ASHP has opposed the practice of sampling for some time. ASHP recognized the following as among the principal drawbacks of sampling:

1. Sampling serves no real health need for American consumers.

2. Lack of control over the distribution of samples creates major health risks related to improper storage and product adulteration, legal inability to properly inspect physicians' samples, and increased risk of distributing expired products.

3. Use of samples increases the costs of drug products.

4. Samples provide access to prescription drugs by unauthorized, untrained personnel.

5. Samples are rarely provided in childproof containers, thus creating an additional health risk.

For more than 12 years, ASHP has called for elimination of sampling. In May 1979, during hearings before the Subcommitte on Health and Scientific Research of the Senate Committee on Labor and Human Resources, ASHP voiced its strong support for proposed legislation that would have substantially restricted the distribution of free drug products. In November 1985, in response to the resurgence of samples as a known public health risk, ASHP's Board of Directors unanimously reaffirmed the Society's decade-old policy on samples.

In short, while ASHP recognizes the complexities involved in other segments of the drug diversion scandal, we believe that the issue of sampling offers Congress a unique opportunity to eradicate at least this aspect of the problem. It is clear that any purported benefits of sampling are far outweighed by the public interest in eliminating the risks involved with the continuation of the practice. While the proposals regarding sampling in S. 368 and H.R. 1207 will improve the current situation, ASHP recommends that Congress consider prohibiting distribution of sample drug products altogether.

Reimportation of Drugs

ASHP is pleased that both S. 368 and H.R. 1207 would, in effect, prohibit the practice of reimporting prescription drugs into this country. Congress has correctly discerned that ensuring the safety and efficacy of the products and protecting the integrity of the nation's drug distribution system far overshadow any economic benefits of reimportation.

Unit-of-Use Packaging

ASHP first considered the issue of unit-of-use, or treatment-size, packages in 1973 and in 1975 adopted a policy encouraging such packaging. Among the reasons we adopted this policy were our belief that such packages are (1) safer for the patient and (2) time-saving for the pharmacist, thereby freeing more time for

patient counseling and education and related professional activities. Unfortunately, treatment-size packages have not been forthcoming from the industry. Aside from these profession-based reasons for such packaging, other reasons stemming from the House hearings indicate why unit-of-use or treatment-size packages should be given a fresh look. We believe unit-of-use packaging could help reduce "gray market" abuses by making it far more difficult for diverted samples and counterfeit drugs to be repackaged, thus removing a major part of the economic incentive underlying such activities.

We do not feel unit-of-use should be mandated by legislation, but we hope that the utility of treatment-size packages will be favorably reevaluated by industry and pharmacy.

Conclusion

By now, everyone is keenly aware that the public health problems raised by "gray market" situations in which drugs travel outside bona fide channels of distribution is no mere theoretical "issue" but a catastrophe waiting to happen. To the extent the associations before you have members who tolerate, participate in, or permit a "gray market" to survive, we must share the consequences of those actions; however, the task before us is not laying blame but finding solutions.

The American Society of Hospital Pharmacists believes this problem can be solved through action within the profession and through appropriate legislation. Within pharmacy's own house we believe the following things can be done:

1. Pharmacists should assume an ethical responsibility to refuse to deal in the "gray market;" gray market "deals" should be reported to state regulatory boards.

2. State regulatory boards should move more aggressively against individual pharmacists and pharmacies who trade in "gray market" pharmaceuticals.

3. Manufacturers and wholesalers should use computer technology to more effectively track products and discern unusual purchases or fluctuations in commerce that might indicate infusion of counterfeits or samples into the chain of distribution.

4. The utility of treatment-size packages should be reassessed and voluntarily established as a standard packaging mechanism.

5. Manufacturers should cease sampling.

Additionally, it is clear to us that legislation embodying the principal provisions contained in S. 368 and H.R. 1207 is essential. Final legislation minimally should:

1. Impose substantial civil and criminal penalties upon those who deal in the "gray market."

2. Prohibit or strongly restrict sampling so that sample products are not put into the marketplace.

3. Mandate that all returned goods and imports be tested for strength, quality, and priority before admission to domestic commerce.

We recognize that these recommendations are stringent and, unfortunately, that some hospital pharmacists may find themselves feeling the brunt of these sanctions. Our responsibility lies not in protecting hospital pharmacists but, as professionals, in protecting the public health. We believe that our recommendations, if followed through by Congress and pharmacy, will stop--unequivocably stop--an unnecessary and dangerous flaw in the integrity of the system of drug distribution and control.

Mr. Chairman, we offer our fullest cooperation in working with this Subcommittee and appreciate the opportunity to appear before you. Thank you.

STATEMENT OF CALVIN J. ANTHONY, MEMBER, EXECUTIVE COMMITTEE, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS AND CHAIRMAN, NATIONAL LEGISLATION AND GOVERNMENT AFFAIRS COMMITTEE, ALEXANDRIA, VA

Mr. ANTHONY. Thank you, Mr. Chairman. I am Calvin Anthony, and I am a community pharmacist from Stillwater, Oklahoma. I am a member of the Executive Committee of the National Association of Retail Druggists and serve as our National Legislation and Government Affairs Committee Chairman.

The subject of today's hearing, The Prescription Drug Marketing Act of 1987, is bipartisan legislation that addresses the very top priority of independent retail pharmacists in the United States in that it prohibits the resale of drugs purchased by health care institutions and charitable institutions from the selling or trading of drug samples.

We commend you, Senator, for the leadership that you have provided in introducing this legislation into the 99th Congress in January of this year in Senate bill 368 and also the 19 Senators who to date have cosponsored this legislation.

As a bottom line matter, we agree in the recent comment to our legislative conference on March 23 when you said that prescription drug diversion presents a pernicious threat to the health and well-being of the American people and to the hard-earned trust which they have been accorded to the members who represent them.

Our primary interest, Senator, in this legislation is the section which would prohibit resale of pharmaceuticals by hospitals and other health care entities or charitable organizations, including bogus charities. This provision is intended to cover resales by both for-profit and nonprofit health care entities. The institutions typically receive discount prices, substantially below the average wholesale price for pharmaceuticals based on their status as a health care entity or charity. When hospitals or other health care entities obtain the pharmaceuticals at these favorable prices, and then resell those drugs at a profit, they are unfairly competing with wholesalers and retailers who cannot obtain such a favorable price.

These resales reward the unscrupulous and penalize the otherwise honest and efficient wholesaler or retailer while fueling the diversion market. These special prices are not available because of volume purchases, but they are the result of price discrimination that is available through a perversion of an era law that forgave price discrimination crimes which benefitted charities.

Charity in today's environment, in our view, would include nonprofits only to the extent that they are providing uncompensated care. It is the availability of prescription drugs and other products at such radically reduced costs or virtually, in some cases, no cost that entices most criminals targetted by these provisions.

We have included in our testimony, which is submitted for the record, a chart of a price list which demonstrates the average range of price discrimination involved: in one to ten, or in extreme cases, even one to a hundred.

For example, Mr. Chairman, Transdern Nitro, which is a nitroglycerine patch used in my drug store, I can purchase for approxi-

mately a price of $40.00 for a month's supply; but it is available through the discriminatory pricing mechanism at a price of approximately 30 cents to supposedly charitable hospitals. In our view, no organization, including those that serve to some extent charitable purposes, should we allow to flaunt current laws by buying and selling drugs or other products at discriminatory prices and resell their excess quantities into the diversion black market.

The type of conduct targetted by the legislation does not involve borderline cases. Typical, for instance, was the case of a 12-bed Florida nonprofit hospital that ordered and received a 42-year supply of an anti-epilepsy drug in a six month period and a 38-year supply of a tranquilizer in an eight month period. Many of the violators are quite bold.

In January of 1987, in an issue of Drug Topics, the Director of the Pharmacist Services of a nonprofit Rhode Island health group association bragged openly that they were diverting so-called "charity drugs" into health centers, each of which has a pharmacy; and because we enjoy the nonprofit status, he said, we have been able to negotiate price reductions of as much as 90 percent of the wholesale price. We believe that the bipartisan compromise regarding the availability of prescription drug samples reflected in the House bill is a pragmatic one; and to the extent it is necessary to ensure enactment, we support it.

We do suggest possible amendments that would achieve the following purposes: Number one, require the destruction of any diverted drugs found to be adulterated or misbranded; but if the product proved to be safe and efficacious, require that they be used for true charitable purposes; and second, require the development of a guide for consumers and pharmacists which would assist them in reporting these illegal diversion activities to the United States Attorney. Such a guide would improve the nature of the element of various offenses, the type of evidence required for prosecution, and an outline of steps to take for a person who has become aware, for example, of prescription drugs.

And third, to make ineligible for Medicare and Medicaid reimbursement any nonprofit institute convicted of violating the resale provision.

Mr. Chairman, we think if the consumer really knew of the price discrepancies in the market today versus the nonprofit entities and those who buy preferentially, that there would be an uprising. And such multiple discriminatory practices still are the rule; and so long as they are, they will tempt drug diverters with easy illegal profits.

And the most tragic part, Mr. Chairman, I think is that people who come into my store and price this product, when I sell it at 10 percent above cost, and they go down the street and purchase it from someone who has diverted merchandise and sells it for half of what I do, they come back and think I am the original Jesse James of pharmacy. And it makes us as pharmacists look to be thieves, and that flies in the face of every decent, honest pharmacist.

I thank you. We believe that the Matsunaga-Dingell legislation will go a long way toward solving this problem by establishing these felony penalties for nonprofit organizations and others who

sell to diverters. And we thank you very much. I will be glad to answer any questions.

Senator MATSUNAGA. Thank you, Mr. Anthony. We shall now hear from Mr. Kelley.

[The prepared written statement of Mr. Anthony follows:]

STATEMENT OF CALVIN J. ANTHONY

BEFORE THE SENATE FINANCE COMMITTEE

SUBCOMMITTEE ON INTERNATIONAL TRADE

THE PRESCRIPTION DRUG MARKETING ACT OF 1987

JUNE 15, 1987

Mr. Chairman, Members of the Subcommittee*:

I am Calvin Anthony. I am a member of the Executive Committee of the National Association of Retail Druggists and serve as Chairman of our National Legislation and Government Affairs Committee. With me today is John Rector, General Counsel and Vice President of Government Affairs.

Thank you for this opportunity to present the views of the owners, managers and employees of 30,000 independent pharmacies, where more than 75,000 pharmacists dispense 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily and provide 82 percent of Medicaid pharmaceutical services. Over 60 percent of NARD's members provide home health care pharmacy products and services. NARD has long been acknowledged as the sole advocate for the proprietary and professional interests of this vital component of the free enterprise system.

NARD members are primarily family businesses. They have roots in America's communities. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness that has made our country great.

The subject of today's hearing, the Prescription Drug Marketing Act of 1987, is legislation that addresses the top priority of independent retail pharmacists in the United States.

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* Spark M. Matsunaga (D-HI), Chairman

MAJORITY: (10-R) Senators Matsunaga, Lloyd Bentsen (LA), Daniel P. Moynihan (NY), Max Baucus (MT), David L. Boren (OK), Bill Bradley (NJ), George J. Mitchell (ME), Donald W. Riegle, Jr., (MI), John D. Rockefeller IV (WV), and Thomas A. Daschle (SD)

MINORITY: (8-D) Senators John C. Danforth (MO), Bob Packwood (OR), William V. Roth, Jr. (DE), John H. Chafee (RI), John Heinz (PA), Malcolm Wallop (WY), William L. Armstrong (CO), and David Durenberger

Independent pharmacists from across the nation gathered at the NARD House of Delegates, in Louisville, Kentucky on October 2, 1986 and unanimously approved the following policy recommendation of the Committee on National Legislation and Government Affairs:

SUBJECT: Discriminatory Pricing, Drug Diversion, and Unfair Competition

RECOMMENDATION: NARD should continue its leadership role in the effort to enact federal legislation to help ensure that no legitimate competitors of independent retail pharmacists are able to acquire prescription drugs and other health care products or services at discriminatory prices. Enactment of the Prescription Drug Marketing Act (H.R. 4820 by Dingell et al., and S. 2875 by Matsunaga et al.) and H.R. 4482 (by Luken) should continue to be NARD's top legislative priority.

NARD should emphatically state its case that 1) the availability of such products at discriminatory prices is the root cause of drug diversion, predatory pricing, captive referral schemes, and other repugnant manifestations of unfair competition; and 2) as a consequence of unfair competition, retail customers, who are already paying higher income taxes to subsidize tax-exempt institutions, not only suffer potential health hazards but must pay unnecessary high prices.

To assist in this priority legislative campaign, NARD should increase its efforts to assist NARD members to identify allies in their communities, including consumer groups, but especially those businesses whose customers are similarly victimized (for example, travel agents or hearing aid dealers) by the anti-competitive practices of non-taxpaying institutions.

This bipartisan legislation, known as the drug diversion act, would:

1) prohibit the resale of drugs purchased by health care institutions and charitable institutions, and the selling or trading of drug samples;

2) prohibit the reimportation of American-made drugs sold for use overseas, except in a bona fide emergency; and

3) require wholesalers to disclose the sources of all drugs they purchase.

We are pleased to appear before the subcommittee. We would like to express our special appreciation to the subcommittee, its chairman and staff for today's timely hearing on this necessary, yet non-controversial legislation.

We commend Subcommittee Chairman Spark Matsunaga for the leadership he has provided in introducing the legislation in the 99th Congress, [1] and in January of this year as S. 368, [2] and the 19 Senators [3] who to date have cosponsored the legislation. We know that Senator Matsunaga has worked closely with House Energy and Commerce Committee Chairman John Dingell

and the Oversight Subcommittee which in the words of the Health and the Environment Subcommittee Chairman Henry Waxman on May 4, when the House bill H.R. 1207 was approved, indicated that the subcommittee had conducted "one of the most extensive investigations the Energy and Commerce Committee has conducted on a health-related matter." We agree with Chairman Dingell's summary, that the purpose of this legislation is "to protect American consumers from mislabeled, subpotent, expired, or counterfeit pharmaceuticals, which are being dispensed under existing law and practice, and to restore competitive balance in the marketplace."

As a bottom line matter, we agree with Senator Matsunaga's recent comment to our legislative conference on March 23 4 that, "prescription drug diversion presents a pernicious threat to the health and well-being of the American people, and to the hard-earned trust which they have accorded to" the members we represent.

Our primary interest in the legislation is the section which would prohibit resales of pharmaceuticals by hospitals and other health care entities or charitable organizations, including bogus charities. This provision is intended to cover resales by both for profit and nonprofit health care entities. The institutions typically receive discount prices, substantially below the average wholesale price (AWP) for pharmaceuticals, based on their status as a health care entity or charity. When hospitals or other health care entities obtain pharmaceuticals at favorable prices and then resell those drugs at a profit, they are unfairly competing with wholesalers and retailers who cannot obtain such a favorable price. Such resales may defraud manufacturers, who are led to believe that the drugs are in accord with current law and for the use of the health care entity, such resales facility predatory pricing. 5 In any case, these resales reward the unscrupulous and penalize the otherwise honest and efficient wholesaler or retailer while fueling the diversion market. 6

In contrast to current limited available sanctions, for example, mail and wire fraud or the RICO statute, the clearly delineated offenses and appropriate sanctions of S. 368 will, in our view, provide both the general and specific deterrent necessary to help curb the havoc that such pricing practices have spawned, both in terms of unfair competition and the threat to consumer health and welfare posed by the risk of adulterated and substandard quality diverted drugs.

These special prices are not available because of volume purchases but are the result of price discrimination that is available through a perversion of an era law that forgave price discrimination crimes which benefitted charities.

In 1936, Congress determined that large sellers and buyers in the drug and grocery marketplace were exercising substantial buying power in a way that discriminated against small buyers. Congress enacted the Robinson-Patman Act to make it unlawful for a seller to sell to a customer who would, in turn, resell in competition with another customer at a discriminatory price.

In 1938, Congress passed an exemption to the Robinson-Patman Act to address a concern that charitable institutions -- that had previously obtained goods from sellers at lower prices because they were used for eleemosynary or charitable purposes -- would not be able to do so as a result of the passage of the Act. These institutions, typified by almshouses or pauper hospitals, were supported by subscription and were making their services available to people who could not pay for the services. Today, nonprofits that are engaging in commercial activities with for-profit firms that pay federal, state and local taxes for the privilege of doing business, claim the protection of that exemption. That claim flies in the face of the purpose of the exemption and their method of operation. Few, if any, patients receive free care from such organizations. In order to obtain care from them, they must be a paying member, or be covered by Medicare or Medicaid. To call Kaiser or AARP, for example, charities for 1938 Act purposes, is to abuse the term.

Charity in today's environment, in our view, would include nonprofits only to the extent they are providing uncompensated care. It is the availability of prescription drugs and other products at such radically reduced costs or virtually no costs, that entices most of the criminals targeted by these key provisions of the legislation:

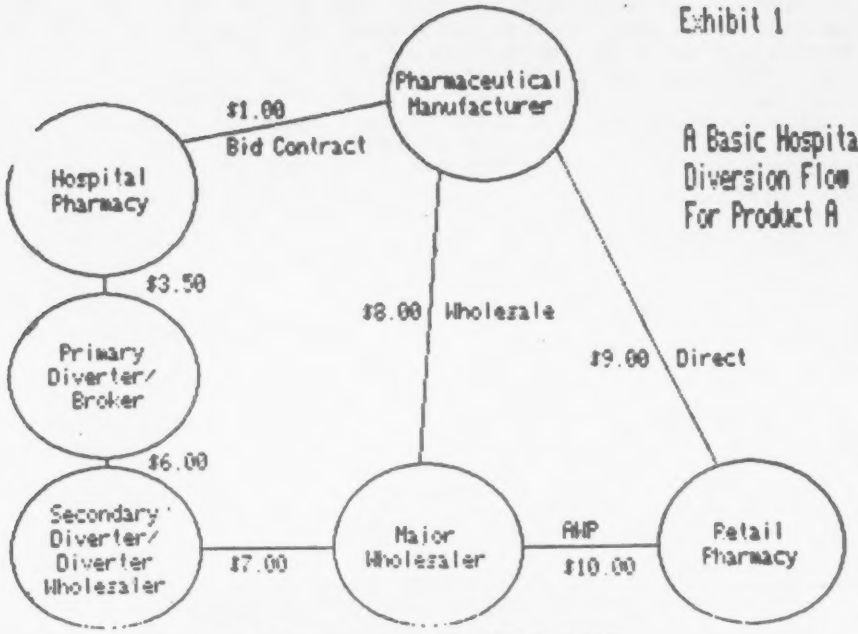
-- without the benefit of price discrimination, a nonprofit institution would not buy in excess of its needs and illegally resell the surplus.

-- without the benefit of price discrimination, companies or individuals would have little or no incentive to obtain pharmaceuticals from manufacturers through false or fraudulent pretenses.

-- without the benefit of price discrimination, what incentive would there be to re-export back to the United States pharmaceuticals produced in the U.S. and sold to foreign buyers?

-- without the benefit of price discrimination, no diversion black market would exist to facilitate the introduction into the drug distribution system of adulterated, counterfeit, and stolen prescription drugs.

The scope of discriminatory prices presently available to 6000 (of 7000 total U.S. hospitals) nonprofit hospitals and 228 nonprofit HMOs (of 342 total U.S. HMOs) is highlighted in the following price comparison between the wholesale prices available to our members and the contract prices available to ostensible charities. The accompanying graphic (see next page) presented to the House Subcommittee on July 10, 1985 by its special investigators, Stephen Sims and David Nelson, portrays a typical drug diversion scam. However, the variety of such conspiracies is limited only by the creativity of criminal minds.



STATEMENT OF STEPHEN F. SIMS AND DAVID W. NELSON
BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE COMMITTEE ON ENERGY AND COMMERCE, July 10, 1985

PHARMACEUTICAL DIVERSION

EXHIBIT 1

PRODUCT ANALYSIS BY TIER PRICING

Product	AWP ($)	Contract ($)
Tylenol tabs., 325 mg., 1000	32.54	2.84
Proventil inhaler, each	9.18	2.95
Omnipen-N, inj., 1g., 10s	148.69	35.70
Velosef, 250 mg. caps., 100s	38.71	14.80/10
Lotrimin 1% cream, 15 g. each	5.27	.99
Garamycin, 80 mg./2 ml. inj.	84.50	10.20
Alupent tabs., 10 mg., 100s	12.22	2.99
Depo-medrol, 40 mg. inj.	4.95	2.30
Transderm Nitro, 2.5 mg.	28.70	.30
Nilstat Susp., bowel	13.84	1.78
K-Lor, 15 mg., 100	28.58	3.50
K-Tab, 10 mg., 100	10.44	.62
Kaon-ce tabs, 100	9.49	3.00

Reference: Statement of Eddie Ronald Burklow before the House Subcommittee on Oversight & Investigations, Committee on Energy & Commerce, September 19, 1985

Typically our members, independent retail pharmacists, pay $9-10, depending on whether they purchase directly from a manufacturer or from a wholesaler, and a nonprofit hospital pays $1 for the same prescription drug. In the case of Transderm Nitro, the ratio is nearly 1 to 100. Unless wholesalers or retailers purchase prescription drugs that have been illegally diverted from nonprofit hospitals, such "discounts" are unavailable to them, irrespective of the volume purchased.

What is the extent of such sales? In a recent calendar year, manufacturer's sales of prescription drugs for human use in the United States totaled $15,393.7 million. Sales to hospitals, nonprofit and government, exceeded 20% of this total. Private hospitals, the overwhelming majority of which enjoy nonprofit status, held a 13.7% marketshare, with total purchases of $2,107.9 million.

Such pricing policies lend to phenomenal cost-shifting to the general public, created by the extraordinary low prices offered to nonprofit institutions purchasing prescription drugs.

The possible dimensions of cost shifting to wholesale and retail purchasers is best assessed when it is recalled that typical differential means that the retailers pay in the range of $10 for every $1 paid by a non-profit hospital for the same product. Thus, in terms of the normal wholesale/retail marketplace, the value of such purchases by nonprofit hospitals could approach that of all sales of prescription drugs. Think for a moment -- if even 50% of the hospital purchases were acquired at a 10 to 1 ratio, the 2.1 billion reported would convert in value to more than $10 billion.

Some major pharmaceutical corporations have a one-price policy. Recently, an additional major pharmaceutical corporation announced that it would significantly increase its so-called "bid prices". The corporation indicated that in moving towards a one-price policy, they hope to minimize the present competitive disadvantages to retail pharmacies and their patient/customers, who presently experience frequent price increases for their prescription drugs.

Our members, unfortunately, are taking it on the chin from the paying public for such drug price increases. An to add insult to injury, in the end consumers pay twice -- first in taxes to subsidize commercial nonprofits; then again, in increased drug prices due to manufacturer's cost shifting. Even hospital patients pay extraordinarily high prices for prescription drugs; especially when one considers the extraordinary discounts at which the products are purchased.

In our view, no organization, including those that serve to some extent charitable purposes, should be allowed to flaunt current laws by buying and selling drugs and other products at discriminatory prices and reselling excess quantities into the diversion black market. The type of conduct targeted by the legislation does not involve borderline cases.

Typical, for instance, was the case of a 12-bed Florida nonprofit hospital that ordered and received a 42-year supply of an anti-epilepsy drug in a six-month period and a 38-year supply of a tranquilizer in an eight-month period!! Thus, it is the multitier pricing structure for pharmaceuticals which "provides the principal economic incentive for prescription drug diversion."[7]

Many of the violators are quite bold. In a January 1987 issue of the publication DRUG TOPICS, the Director of Pharmacy Services at a nonprofit Rhode Island group health association bragged openly that they were diverting so-called charity drugs into health centers, each of which has a pharmacy, and "because we enjoyed the nonprofit status, we've been able to negotiate price reductions of as much as 90% off wholesale price."

Bogus charities are also involved. For example, the investigation revealed prosecutions brought by the U.S. Department of Justice against corporate officials of a drug wholesale company who fraudulently represented that they were purchasing drugs at charity prices for the Indiana Chapter of AARP. These drugs were diverted into the illegal market and eventually the corporate officials were sent to prison. As if to add insult to injury, the irony of this bogus charity scheme is that AARP hardly qualifies as a charity under the special 1938 exemption to the antitrust price discrimination sanctions.[8]

In addition to the matter of resales, we believe that the bipartisan compromise regarding the availability of prescription drug samples reflected in the House bill is a pragmatic one and to the extent it is necessary to ensure enactment, we support it. Additionally, it is notable, that under the legislation, physicians and others, irrespective of state law, would be subjected to serious felony sanctions for selling prescription drug samples. Physicians were, however, permitted continued access to such samples to appropriately assist patients in emergencies and circumstances requiring immediate initiation of drug therapy.

In a July 16, 1986 letter to Chairman Dingell regarding H.R. 4820, AMA Executive Vice President Dr. Sammons presented the eventually adopted case, in part as follows:

> "Drug samples provide many benefits for patients. Samples allow a physician to begin therapy immediately, which could be very important, particularly on a weekend, holiday, or evening when most (sic) pharmacies are not open. Samples also permit a physician to initiate therapy with a small amount of a drug and determine the patient's therapeutic response and tolerance before prescribing larger amounts for full course of treatment. This is important from the standpoint of drug efficacy, safety and cost."

We do suggest, however, amendments that would achieve the following purposes:

1) Require the destruction of any diverted drug found to be adulterated or misbranded, but if the products prove to be safe and efficacious, require that they be used for true charitable purposes;

2) Require the development of a guide for consumers and pharmacists which would assist them in reporting illegal diversion activities to United States Attorneys. Such a guide could include the nature and elements of the various offenses, the type of evidence required for prosecutions, and an outline of steps to take once a person has become aware, for example, of prescription drugs for sale that are labeled "For Hospital Use Only"; and

3) Make ineligible for Medicare/Medicaid reimbursement any nonprofit entity convicted of violating the resale provisions of S. 368.

The ultimate victim of a drug diversion scheme is the consumer. Every American family is affected not only by the high cost of prescription drugs, but by a myriad of public health consequences that are inevitable when such fraudulent procurement schemes take drugs out of the legitimate drug distribution system. Manufacturers are not able to trace the drugs in the event of a recall. Regulatory agencies aren't able to monitor diverted drugs to account for proper storage and handling to preserve drug efficacy.

The former U.S. Attorney in Atlanta, at the October 31, 1985 Oversight Subcommittee hearing "also dispelled the myth that drug diversion can be the consumer's friend by mitigating against the high cost of prescription pharmaceuticals, since the drugs are resold through many levels of the distribution chain, with each intermediary extracting a profit."[9]

The radically low purchase prices are not passed on to the ultimate consumer. In fact, few, if any, experience a discount after the chain of criminal diverters has extracted its profits. The losses of the defrauded manufacturers are passed on to NARD members and ultimately to the public through higher prices -- prices that are already artificially higher in order to sustain the current industry practice of price discrimination for select nonprofits.

But such multitier discriminatory pricing practices still are the rule, and so long as they are, they will tempt drug diverters with easy, illegal profits. The Matsunaga/Dingell legislation goes a long way toward solving this problem by establishing serious felony penalties for nonprofit organizations and others who resell drugs to diverters. NARD hopes that this legislation will encourage other manufacturers to adopt a one-price policy, incorporating, of course, legitimate volume and other discounts, for all their customers.

NARD urges the subcommittee to approve the Matsunaga/Dingell legislation and seeks the support of the subcommittee for our recommendations. As a member of the Industry Coalition on Drug Diversion, we offer our assistance to its members and staff in the refinement of the legislation, especially in the area of resale made possible by price discrimination.[10]

In the meanwhile, and even after the enactment of the Matsunaga/Dingell legislation, we remind all concerned, as NEWSWEEK magazine did in December 1985 that, "...the consumer's best defense against drug diversion is to find a reputable pharmacist and be suspicious of deep discounts."

On behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to appear and to participate in the development of regulatory and legislative reform which will protect the consumer from the health consequences of drug diversion, and the economic consequences of predatory pricing and cost shifting resulting from subsidized sales to nonprofit entities.

STATEMENT OF TY KELLEY, VICE PRESIDENT OF GOVERNMENT AFFAIRS, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, ALEXANDRIA, VA

Mr. KELLEY. Mr. Chairman, my name is Ty Kelley. I am Vice President of Government Affairs for the National Association of Chain Drug Stores. We commend you for the leadership role that you have taken on this important consumer protection issue and for expeditiously scheduling these hearings, following approval last month of The Prescription Drug Marketing House by the House of Representatives.

I will briefly summarize. Our corporate drug chain members strongly believe that the legislation pending before this subcommittee is absolutely necessary because it will do the following. Number one, strengthen existing laws that have in recent years proven to be terribly inadequate. Two, restore integrity and order in the U.S. drug distribution system, which has been grossly influenced by the 1938 statute relating to preferential pricing policies. And three, curtain numerous marketing abuses, primarily in the area of physician drug samples.

As evident by the extensive hearings that were held by the House Energy and Commerce Subcommittee on Oversight and Investigations, brand name manufacturers' preferential pricing policies and physician drug samples are the driving force that fuels the diversion market. Not only are consumers at risk when prescription drugs are diverted from normal channels of distribution, but we also must contend with the resulting effect of higher prices to the general public, to needy recipients and the elderly as greater shares of a manufacturer's sales go into the nonprofit area.

To the extent that The Prescription Drug Marketing Act places reasonable limits on nonprofit hospitals to prohibit the resale of pharmaceuticals, either donated to these entities or obtained at generous discounts from manufacturers, we wholeheartedly support the legislation. Of equal importance, the legislation clearly establishes needed reforms to govern physician drug samples. The existing system of providing samples to doctors through manufacturers' sales reps invites abuses, as these products are openly traded and sold as well as improperly stored and eventually either adulterated or misbranded, which threatens the health and safety of patients.

In that the legislation provides for needed control over physician drug samples and bans the selling and trading of these commodities, we endorse the bill. In our view, consumers will remain at risk until the Congress adopts The Prescription Drug Marketing Act of 1987.

Much effort already has been put forth by Chairman John Dingell, Mr. Waxman, and others in the House in terms of this legislation to minimize the potential for substandard, mislabeled, or counterfeit drugs to enter the stream of commerce. As the ultimate providers of the final product to the consumer, our corporate members share the same concerns that you, Mr. Chairman, have expressed with regard to guaranteeing legitimacy and integrity of prescription drug products that chain pharmacies dispense to patients.

We, therefore, strongly support enactment of The Prescription Drug Marketing Act of 1987 and urge the subcommittee to favorably report the legislation. Thank you.

Senator MATSUNAGA. Thank you very much, Mr. Kelley, and I certainly wish to thank each and every one of you for your strong support of The Prescription Drug Marketing Act.

As I understand it, Mr. Streck, you say you prefer the language of the House bill? Is that correct?

Mr. STRECK. Yes.

Senator MATSUNAGA. And is that the feeling among the others also? Mr. Schlegel?

Mr. SCHLEGEL. Yes. The amendments to H.R. 1207 were amendments that were largely negotiated out by many of us in the room today; and we feel that that would strengthen your bill rather significantly.

Senator MATSUNAGA. Mr. Gans, do you feel the same?

Mr. GANS. We like the sampling provisions in your bill over what is in the House bill.

Senator MATSUNAGA. The sampling provision?

Mr. GANS. Yes.

Senator MATSUNAGA. I see. And Mr. Anthony?

Mr. ANTHONY. Yes, sir. We are comfortable with the House bill.

Senator MATSUNAGA. Mr. Kelley?

Mr. KELLEY. In that Section 6 would, I believe, apply to some of our corporate members who have distribution centers, we feel that the House language is much better and would resolve a number of problems.

Senator MATSUNAGA. And of course, we have heard here how The Prescription Drug Marketing Act will protect the consumer. Now, how will it affect the reputable pharmacist if we do pass the Act? Will it be of assistance to you in maintaining a reputation for selling good drugs? I take it that this will be what you were seeking in the bill? Mr. Schlegel?

Mr. SCHLEGEL. Yes. We take great pride in the United States of having the best drug distribution system in the world, and anything that erodes that makes any of us in the health profession feel uncomfortable.

Senator MATSUNAGA. Good.

Mr. SCHLEGEL. So, I think our argument would be to move quickly for legislation.

Senator MATSUNAGA. Mr. Streck, do you agree?

Mr. STRECK. I certainly do.

Senator MATSUNAGA. And Mr. Gans?

Mr. GANS. Anything that is going to improve the public confidence in the drug product is going to improve our image, and I think that is going to be helpful.

Senator MATSUNAGA. Mr. Anthony?

Mr. ANTHONY. Yes, sir. I think it is a very important aspect of the bill, Senator. I think that the image of credibility that it will help us continue is very, very critical.

Senator MATSUNAGA. And Mr. Kelley?

Mr. KELLEY. I would echo the same remarks that have been made by my colleagues at this table.

Senator MATSUNAGA. Good. Thank you all. You have been very helpful to the subcommittee, and you can rest assured we will do all that is possible as fast as possible.

Mr. SCHLEGEL. Thank you, sir.

Senator MATSUNAGA. Our third and final panel of witnesses consists of pharmaceutical manufacturers. They are Mr. Gerald Mossinghoff, President of Pharmaceutical Manufacturers Association, and Mr. Daniel J. Desmond, Member of the Board of Directors of the National Pharmaceutical Alliance which represents the manufacturers of generic drugs.

Senator MATSUNAGA. Mr. Desmond, we appreciate your coming all the way from Indiana. As I understand it, you have a plane to catch; so maybe we will hear from you first.

[The prepared statement of the National Association of Chain Drug Stores, Inc. follows:]

Statement of the National Association of Chain Drug Stores, Inc.

BEFORE THE SENATE FINANCE COMMITTEE

SUBCOMMITTEE ON INTERNATIONAL TRADE

THE PRESCRIPTION DRUG MARKETING ACT OF 1987

(S. 368 - H. R. 1207)

June 15, 1987

NACDS
National Association of Chain Drug Stores, Inc.
P.O. Box 1417-D49
Alexandria, Virginia 22313
703-549-3001

INTRODUCTION

Mr. Chairman and Subcommittee Members, the National Association of Chain Drug Stores, Inc., (NACDS) is pleased to testify on the Prescription Drug Marketing Act of 1987. We commend the Chairman for the leadership role he is taking on this consumer protection issue and for expeditiously scheduling these hearings following approval last month of H. R. 1207 by the House of Representatives.

NACDS is a non-profit trade organization, founded in 1933, which represents the management of 171 chain drug corporations that are operating close to 20,000 retail drug stores and pharmacies throughout the United States. Collectively, our members were responsible for $30 billion in retail sales in 1986 and more than 540 million prescriptions were dispensed to patients by corporate drug chains during this same period. Also, 50,000 pharmacists practice their profession for our member companies.

NEED FOR ENACTMENT OF THE PRESCRIPTION DRUG MARKETING ACT

During the 99th Congress, the House Energy and Commerce Subcommittee on Oversight and Investigations held a series of eight hearings on the issue of drug diversion. The Subcommittee, chaired by Rep. John Dingell (D-Mich.) collected extensive information and received testimony from numerous organizations and law enforcement authorities which raised significant health and safety issues that relate directly to the diversion of

pharmaceutical products in the United States. Based on these hearings, the House Subcommittee identified numerous problems stemming from drug diversion that place consumers at risk. They include safety, efficacy, storage, and the handling of brand-name pharmaceutical products. More specifically, the Subcommittee found that drug diversion can result in consumers receiving mislabeled, subpotent, adulterated, expired, and counterfeit medications. Fortunately, while diversion is widespread, documented incidents of harmful or ineffective prescriptions reaching patients are few. Nonetheless, the legislation pending before the Senate Subcommittee is absolutely necessary because it will do the following: (1) strengthen existing laws that have been proven inadequate; (2) restore integrity and order in the United States drug distribution system that has been influenced by a 1938 statute concerning preferential pricing policies and non-profits; and (3) curtail numerous marketing abuses relating primarily to physician drug samples.

PREFERENTIAL PRICING -- SAMPLING ABUSES

In particular, the House Subcommittee on Oversight and Investigations found that preferential pricing policies by brand-name manufacturers is a driving force that fuels the diversion market. Sanctioned by Federal law, non-profit hospitals, nursing homes, clinics and other health care facilities, including HMO's are allowed to purchase drugs at significant discounts directly from pharmaceutical companies. These discounts are often 60 percent or greater than the best price that corporate drug chains receive from the manufacturer. Because of this buying advantage, many non-profits will purchase large quantities of drugs at a preferential

price and resell the products to diverters and other businesses for economic gain. These excessive purchases which are far beyond the needs of the non-profit health care facility to care for its patients, are often used in direct competition against retail pharmacies. While accountability as to the product source in the secondary market is lacking as a result of preferential pricing abuses, problems relating to physician drug samples are equally disturbing. The temptation to buy, sell and trade pharmaceutical samples for economic gain is substantial since it is currently not a Federal offense to barter in these commodities. Unfortunately, the sale and diversion of samples often leads to adulteration and misbranding. Moreover, lack of accountability and the removal of the product from its packaging can result in the drug becoming subpotent, or contaminated and very difficult to recall.

The House Subcommittee in its investigation has also documented other abuses associated with fraudulent exports and imports as well as bogus charity schemes involving prescription drugs which threaten the health and safety of the American consumer.

KEY PROVISION OF THE DRUG DIVERSION LEGISLATION

To correct these abuses and to protect consumers from receiving substandard, impotent, mislabeled, adulterated, or counterfeit medications the House Oversight Subcommittee under the guidance of Chairman John Dingell developed a comprehensive legislative measure entitled the Prescription Drug Marketing Act during the 99th Congress. A companion bill was introduced by Senator Matsunaga. At that time, NACDS and its corporate members endorsed both

bills. In the 100th Congress, the Chain Drug Industry once again has called for enactment of the so-called Drug Diversion legislation.

In brief, the Prescription Drug Marketing Act of 1987 (S. 368 - H. R. 1207) amends the Federal Food, Drug, and Cosmetic Act to enhance consumer protection with respect to pharmaceutical products that are being marketed and distributed in the United States. These bills ban the reimportation of prescription drugs into this country except in an emergency situation by the manufacturer of the product. The legislation prohibits the sale, purchase or trading of physician drug samples and outlaws the resale of pharmaceutical products that have been either donated or provided at reduced prices to non-profit hospitals, health care facilities and charitable organizations. Other major sections in the legislation provide for important reforms in the distribution of physician drug samples and new standards to govern the distribution, storage and handling of prescription drug products at the wholesale level. Most importantly, the legislation establishes a range of strong criminal and civil penalties for violations of the Act's provisions.

CONCLUSION

Mr. Chairman, NACDS endorses the Prescription Drug Marketing Act of 1987 for the following reasons: (1) the legislation contains many needed reforms that will minimize the potential for substandard, mislabeled, adulterated, or counterfeit drugs to enter the stream of commerce; (2) the bills will bring order and accountability back to the competitive marketplace by prohibiting the resale of drugs that were either donated or provided at

reduced prices by manufacturers to non-profit health care facilities; and (3) the legislation is a very important public health measure that will restore confidence and integrity in the distribution system of prescription drugs.

As the ultimate provider of the final product to the consumer, our corporate members share the concerns that you, Mr. Chairman, have expressed with regard to guaranteeing the legitimacy and integrity of the prescription drug products that chain pharmacies dispense to patients. We, therefore, strongly support enactment of the Prescription Drug Marketing Act of 1987 and urge this Subcommittee to favorably report the legislation.

Thank you.

TK/kar

STATEMENT OF DANIEL J. DESMOND, MEMBER, BOARD OF DIRECTORS, NATIONAL PHARMACEUTICAL ALLIANCE, SEYMOUR, IN

Mr. DESMOND. Thank you. Mr. Chairman, may I first say that our members in part are manufacturers and distributors of branded generic drugs. We see it as three categories. We have the research-based companies, the traditional generic firms, and then the branded generic firms, and that is who I am here to represent today. These are the smaller firms that market name brand products that do require physician specification. As I said, I represent NPA, the National Pharmaceutical Alliance. I am the secretary, but I am a volunteer and employed by a pharmaceutical firm in Indiana.

A brief word about who we are, and I have a written statement, if I may for the record. NPA is an association of approximately 160 small to medium-sized pharmaceutical manufacturers and distributors. Some 34 of our members distribute samples by mail and/or through sales representatives. They are the ones interested in this legislation. Our member companies are not large. In fact, most of them are regional. Their annual sales go from less than $1 million to approximately $15 million, and their sales forces range in size from three to about 90.

Generally speaking, our companies distribute private brands of off-patent prescription drugs which compete with the national brands. Our products are priced lower than the national brands, yet our detail men offer the kind of service and information to practitioners which was heretofore made available only by the national distributors.

My remarks today won't be long because we are not asking for much. Mr. Chairman, let me begin by saying that our members have no quarrel with the efforts made by this legislation to make sure that all drug samples given to detail men for distribution to practitioners actually reach those practitioners and support your efforts to eliminate drug diversions. We frankly do not think that our products are a part of the diversion problem since common sense suggests that anyone going through the risk and trouble to divert prescription drugs would select the national brands which are distributed in large quantities and bring higher prices. By way of example, our companies distribute in blister packs and small containers of from four to six dosage units for solid oral dosage form and in bottles of one or two dosage units for liquid preparations.

The average delivery to a physician from one of our representatives is 18 solid dosage forms or five ounces of liquid preparation. So, the bottom line is that we don't leave much, and the resale value of what we do leave is not that high. But as I said before, we have no quarrel with the legislation; however, we prefer H.R. 1207 and hope the Senate will adopt it. We are aware of the fact that this measure is the result of extended negotiations which were held with PMA. Most of its members are large companies whose concerns are somewhat different than ours.

We simply want to address three areas today in which we feel the bill impacts a bit harshly on smaller companies.

We are confident that this impact is inadvertent, rather than intentional, and we would like to offer for the committee's consideration some report language which would address our concerns; and we have attached it, so I will not read it. The legislation provides that any company whose detail men are convicted three times within a ten-year period for drug diversion can be subjected to a fine of up to $1 million. The House report then states that any internal auditing procedure which is offered as a defense by the company against the assessment of that fine has to meet some high standards which are specifically spelled out in that report.

Among other things, the report says that representatives of the company not associated with the sales division have to make enough visits to the practitioners to establish that the detail men are leaving the samples that they claim to be leaving. The report goes on to state "nor does the committee intend this section to require that a manufacturer or a distributor inquire into the use of samples given to a practitioner by a sales represntative or in any other way intrude into the physician/patient relationship."

I take this to mean that we are supposed to check on the detail men but not the doctors, which is perfectly appropriate. With that being the case, I don't see that the visits have to be in person. In my opinion, mail or phone audits would work over the long haul. We are suggesting a paperwork trail that would make it very difficult to divert whereby a three-part form would be signed by a physician. One part would be sent to the company by the detail man; two parts would be left with the physician's office, one part to be retained by the office; the other would be returned to the pharmaceutical firm by the doctor's office. And then the audits could be made to double check to see if in fact there was not collusion between someone in the office and the detail person. And I will go on.

The company representative is simply going to walk in the door and this would be the auditor. They would simply walk in and ask if the salesman left what he purported to leave, and that could be done by phone or mail, we feel.

Mr. Chairman, I am not here today to nitpick the bill; but as I said, most of our members are small. It is all any of them could do—or at least many of them can do—to keep detail men in the field. If they are required to maintain a field force of auditors, it will place too great a strain on their resources. We are not asking that you do away with physical audits. We are simply suggesting that telephone or mail audits are a viable alternative. When you read the report language we are offering, I think you will agree that the physical record-keeping requirements which are spelled out in some detail, coupled with mail or telephone audit, constitute a procedure which is well within the intent of the framework of the legislation.

Our membership hopes you will see fit to include the language. Earlier in my statement, I mentioned a provision in the statute which calls for the imposition of a fine of up to $1 million. For companies whose detail men are convicted for drug diversion three times in a ten-year period, a fine of that magnitude is not an insignificant penalty for any company; but as I stated earlier, some of our members do not gross that much in annual sales. We are confident that the drafters of the legislation intended to create a deter-

rent which would apply with equal force to small and large companies. We also feel sure that judges who are applying the statute will reflect that intent.

Nevertheless, we would like to suggest some report language which simply provides that judges should not impose a fine on any company whose impact would be greater than that of a $1 million fine on the largest of companies.

Finally, Mr. Chairman, I address one last concern which we as small businessmen have with the House Committee report.

The House report contains a flat prohibition against the practice of allowing the detail man to leave a standing order with the practitioner, which calls for a certain number of samples to be mailed to the practitioner at regular intervals.

NPA understands the reason for this prohibition, but we think a little more flexible approach would be well advised. While most of our companies use detail men to distribute samples to practitioners, we have a few companies who distribute solely through the mail. For those companies, the provisions in the House report relating to standard orders poses a real problem. If distribution of samples by mail is to remain viable, we think that the regulators at FDA should at least have the option of allowing standard orders which are limited both as to quantity and time.

The report language we are suggesting has been included as an attachment to copies of my statement which are being left with the committee. We have discussed these issues with the Food and Drug Administration. They don't see any problem with their enforcing the legislation, with the provisions that we are suggesting and the language.

In closing, Mr. Chairman, I would like to state that these suggestions have been shared with PMA, and they have no problems with them. They are not joining in this presentation because they promised House members they would make no effort to alter the language they agreed on, but they have no quarrel with what we are doing. I have a few more sentences, but that red light has been on for a while. I want to thank you for the opportunity to give my testimony, and I would be happy to answer any questions you may have. Thank you.

Senator MATSUNAGA. Thank you, Mr. Desmond. We will now hear from Mr. Mossinghoff.

[The prepared written statement of Mr. Desmond follows:]

STATEMENT OFFERED BY DAN DESMOND

Mr. Chairman, I am Dan Desmond, Secretary of the National Pharmaceutical Alliance, and I am here today on behalf of the members of NPA.

First, a brief work about who we are. NPA is an association of approximately 160 small-to Medium-sized pharmaceutical manufacturers and distributors. Some 34 of our members distribute samples by mail and/or through sales representatives, and they are the ones interested in this legislation.

Our member companies are not large—in fact, most of them are regional. Their annual sales go from less than one million dollars to approximately fifteen million dollars, and their sales forces range in size from three to about ninety.

Generally speaking, our companies distribute private brands of off patent prescription drugs which compete with the national brands. Our products are priced lower than the national brands, yet our detail men offer the kind of service and information to practitioners which was, heretofore, made available only by the national distributors.

My remarks today won't be long, because we are not asking for much.

Mr. Chairman, let me begin by saying that our members have no quarrel with the efforts made by this legislation to make sure that all drug samples given to detail men for distribution to practitioners actually reach those practitioners.

We frankly do not think that our products are part of the diversion problem, since common sense suggests that anyone who is going to the risk and trouble to divert prescription drugs would select the national brands which are distributed in larger quantities, and bring higher prices.

By way of examples, our companies distribute in blister packs or small containers of from four to six dosage units for solid oral dosage form and in bottles of one to two dosage units for liquid preparations. The average delivery to a physician from one of our representatives is 18 solid dosage forms or five ounces of liquid preparation.

So the bottom line is that we don't leave much and the resale value of what we do leave is not that high. But as I said before, we have no quarrel with the statute.

We are aware of the fact that this measure is the result of extended negotiations which were held with PMA. Most of its members are large companies whose concerns are somewhat different from ours. We simply want to address three areas today in which we feel the bill impacts a bit harshly on smaller companies.

We are confident that this impact is inadvertent rather than intentional, and we would like to offer, for the committee's consideration, some report language which would address our concerns.

The legislation provides that any company whose detail men are convicted three times within a ten year period for drug diversion can be subjected to a fine of up to one million dollars. The House report then states that any internal auditing procedure which is offered as a defense by the company against the assessment of that fine has to meet some high standards which are spelled out with specificity in that report.

Among other things, the report says that representatives of the company, not associated with the sales division, have to make enough visits to the practitioners to establish that the detail men are leaving what they claim to be leaving.

The report goes on to state, "Nor does the committee intend this section to require that a manufacturer or distributor inquire into the use of samples given to a practitioner by a sales representative, or in any other way intrude into the physician/patient relationship."

I take this to mean that we are supposed to check on the detail men, but not the doctors—which is perfectly appropriate. But that being the case, I don't see that the visits have to be in person.

The company representative is simply going to walk in the door, and ask the receptionist or nurse whether the detail man left what he said he did. This can be done just as well, if not better, by phone or mail. In fact, a lot more checks can be made this way, rather than in person.

Mr. Chairman, I am not here today to nit pick this bill. As I said, most of our members are small. It is all many of them can do to keep a few detail men in the field. If they are required to maintain a field force of auditors, it will place too great a strain on their resources.

We are not asking that you do away with physical audits. We are simply suggesting that telephone or mail audits are a viable alternative. When you read the report language we are offering, I think you will agree that the physical recordkeeping requirements, which are spelled out in some detail, coupled with mail or telephone audits, constitute a procedure which is well within the intent of the framers of the legislation. Our membership hopes you will see fit to include that language.

Earlier in my statement, I mentioned the provision in the statute which calls for the imposition of a fine of up to one million dollars for companies whose detail men are convicted for drug diversion three times in a ten year period.

A fine of that magnitude is not an insignificant penalty for any company. But, as I stated earlier, some of our members do not gross that much in annual sales.

We are confident that the drafters of the legislation intended to create a deterrent which would apply with equal force to small and large companies. We also feel sure that judges who are applying this statute will reflect that intent.

Nevertheless we would like to suggest some report language which simply provides that judges should not impose a fine on any company whose impact would be greater than that of a million dollar fine on the largest companies.

Finally, Mr. Chairman, may I address one last concern which we, as small businessmen, have with the House committee report. The House report contains a flat prohibition against the practice of allowing the detail man to leave a standing order

with the practitioner which calls for a certain number of samples to be mailed to the practitioner at regular intervals.

NPA understands the reason for this prohibition, but we think that a little more flexible approach would be well advised.

By this time, it is well documented that branded generic drugs offer a safe and effective alternative to brand name drugs at a significantly lower price.

While most of our companies use detail men to distribute samples to practitioners, we do have a few companies who distribute solely through the mail. For those companies, the provisions in the House report relating to standing orders pose a real problem.

If distribution of samples by mail is to remain viable, we think that the regulators at FDA should at least have the option of allowing standing orders which are limited both as to quantity and time.

The report language we are suggesting has been included as an attachment to the copies of my statement which are being left with the committee.

In closing, Mr. Chairman, I would like to state that these suggestions have been shared with PMA, and they have no problems with them. They are not joining in this presentation, because they promised House Members they would make no efforts to alter the language they agreed on, but they have no quarrel with what we are trying to do.

We do not ask for changes in the statutory language. We simply hope the Senate will agree to this report language which will not dilute the effect of the statute in any way, but will simply make it apply in a more evenhanded way to small business.

I thank you for your time, and will be happy to respond to any questions you might have.

SUGGESTED REPORT LANGUAGE ON AUDITS

The Committee recognizes that the establishment of an independent auditing force which personally visits practitioners' offices may not be a viable option for smaller companies with limited resources.

The purposes to be served by the audit can be realized through telephone audits as well as personal visits as long as the following conditions are met.

In the first place, people in the companies responsible for auditing cannot be part of the sales force, nor can they report back through the sales force.

The detail man would have to fill out a form for each delivery, clearly indicating the date of delivery, the number of units delivered, and the specific drug involved. The detail man would then send this form to the person or persons in his company designated to audit this program.

He would also leave a similar form with the practitioner's representative to be filled out for their records. That form would have a carbon which would be mailed back to the company auditor in a stamped, self-addressed envelope which would also be supplied. The carbon would have to clearly state that it was to be returned through the mail, and not given to the detail man.

The company auditor would then be required to make a statistically significant number of phone calls to the practitioners to determine that records they were receiving in the mail coincide with those in the practitioner's office.

SUGGESTED REPORT LANGUAGE ON PENALTIES

It is not the intention of Congress that the penalty provisions of this statute should be applied in a harsh and indiscriminate way to smaller firms and businesses.

By placing a one million dollar ceiling on the fines to be imposed, Congress has obviously interposed a protection for the larger firms in this country which limits the impact of these fines.

While the statute does not set out any sliding scale of fines which would afford the same degree of protection to smaller businesses, it should be clearly understood that an evenhanded application is desired.

The fine imposed on a smaller company should not do proportionately more damage than the imposition of a one million dollar fine does to the largest companies.

SUGGESTED REPORT LANGUAGE ON STANDING ORDERS

House Report language states that a standing written request from a physician for samples to be distributed periodically would not satisfy the requirements of section 503(d) which sets out the conditions under which the continued distribution of samples to licensed practitioners would be allowed. The Committee feels that a blanket prohibition is overly strong and suggests that some latitude and leeway be preserved so that FDA can address this question in the regulations.

STATEMENT OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, DC

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. My name is Gerald Mossinghoff. I am the President of the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies that discover, develop, and produce most of the prescription drugs used in the United States. Mr. Chairman, you are performing an important public service through your efforts to stop drug diversion. The research-based pharmaceutical industry fully supports the objectives of your legislation. We urge your subcommittee and the Senate to consider this important matter as expeditiously as possible.

PMA supports legislation to prohibit the return of American goods except to the manufacturer, to prohibit the sale or trade of samples, to prohibit the sale or trade of drugs purchased by health care facilities for the use of its patients, and the use and trade of pharmaceutical products sold at a reduced price to a charitable organization.

Such legislation will substantially help to curb the diversion of prescription drugs. Our industry, however, opposes that part of the legislation that would prohibit the distribution of samples to practitioners except by mail or common carrier. We strongly believe that representatives of pharmaceutical companies should be able to continue to distribute drug samples to physicians who request them.

Mr. Chairman, in that we are joined by the American Medical Association; and as you heard Dr. Schlegel say, by the pharmacists professional association, the American Pharmaceutical Association. Samples, as documented in the record of the House Committee on Energy and Commerce, serve a useful medical purpose and benefit both the prescribing physicians and the patients. I explain this in greater detail in my prepared statement, which I hope will appear in the record.

Senator MATSUNAGA. It will appear in the record.

Mr. MOSSINGHOFF. Our industry supports the sampling provisions in The Prescription Drug Marketing Act of 1987, H.R. 1207, which was passed unanimously by the House of Representatives on May 4th of this year. We cooperated fully with Chairman John Dingell of the House Energy and Commerce Committee and with other members of that committee in developing that legislation. We fully support all of its provisions, and we urge the Senate to pass that bill without amendment. H.R. 1207 incorporates in Section 5 the voluntary code for prescription drug sampling practices adopted by our industry last fall. A copy of that code, Mr. Chairman, is appended to my statement.

The code covers the proper distribution of samples, storage, disposal, inventory, and record keeping. Our companies, to the extent they were not already following the practices set forth in the code, began to implement its provisions as soon as it was adopted by their Board of Directors. The House bill permits representatives of pharmaceutical companies to continue to distribute drug samples to physicians under clearly defined and controlled conditions.

The legislation includes civil penalties up to $1 million, as has already been pointed out, to companies whose employees divert

drugs. Mr. Chairman, I outline in the rest of my statement the actual provisions of the legislation. Again, in the interest of time, I will leave that to be put in the record.

The House legislation places significant burdens on those pharmaceutical companies that decide to continue to use representatives to distribute drug samples to physicians. These provisions were not accepted lightly or hastily by our industry, but were worked out in lengthy discussions and negotiations. We strongly believe that this compromise best serves the interests of the patients and physicians by continuing to permit company representatives to distribute drug samples to physicians under clear and controlled and very stringent penalty conditions; and we urge that H.R. 1207 be sent to the President without amendment.

Mr. Chairman, this concludes the brief summary of my statement. I would be pleased to respond to any of your questions.

Senator MATSUNAGA. Thank you very much, Mr. Mossinghoff.

[The prepared written statement of Mr. Mossinghoff follows:]

GERALD J. MOSSINGHOFF
PRESIDENT
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON INTERNATIONAL TRADE
COMMITTEE ON FINANCE

U.S. SENATE

JUNE 15, 1987

Mr. Chairman and Members of the Subcommittee:

I am Gerald J. Mossinghoff, President of the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies that discover, develop and produce most of the prescription medicines used in the United States. I appreciate this opportunity to appear before the Subcommittee and testify on legislation designed to eliminate the diversion of prescription drugs.

Mr. Chairman, you are performing an important public service through your efforts to stop drug diversion. The research-based pharmaceutical industry fully supports the objectives of your legislation (S. 368). We urge your Subcommittee and the Senate

to consider this important matter as expeditiously as possible.

PMA supports legislation to prohibit the return of American goods except to a manufacturer, the sale or trade of samples, the sale or trade of drugs purchased by a health-care facility for the use of its patients, and the sale or trade of pharmaceutical products sold at a reduced price to a charitable organization. Such legislation will substantially help to curb the diversion of prescription drugs.

Our industry, however, opposes that part of the legislation that would prohibit the distribution of samples to practitioners except by mail or common carrier. We strongly believe that representatives of pharmaceutical companies should be able to continue to distribute drug samples to physicians who request them. Samples serve a useful medical purpose and benefit both prescribing physicians and patients.

Typically, a small number of samples is given by a physician to a patient to start the patient on medication before a prescription is filled at a pharmacy. The samples enable a physician to begin immediately to evaluate the effect of a prescription product in a patient, and to identify early any side effects. If a drug is not working as intended or is not tolerated, the medication can be modified without expense to the patient. Samples also enable physicians to initiate immediate therapy in cases of severe pain or infection, and help to defray

the cost of medicine, which is particularly important to low-income patients.

Our industry supports the sampling provisions in the Prescription Drug Marketing Act of 1987 (H.R. 1207), which was passed unanimously by the House of Representatives on May 4, 1987. We cooperated with Chairman John D. Dingell of the House Energy and Commerce Committee in developing that legislation, fully support all of its provisions and urge the Senate to pass the bill without amendment.

The House bill stems from a federal criminal investigation in Georgia and a series of hearings held by the House Energy and Commerce Subcommittee on Oversight and Investigations on the diversion of prescription drugs. In testifying before the Subcommittee on December 6, 1985, PMA noted that some abuse has resulted from improper practices by a limited number of pharmaceutical company sales representatives and health-care practitioners. We urged that legislative remedies be directed at the root of the problem--those few unscrupulous individuals involved in health-care delivery--and not penalize the many patients who benefit from the proper use of samples.

In May 1986, Chairman Dingell introduced legislation (H.R. 4820) to curb drug diversion that would have prohibited the distribution of samples to practitioners except by mail or common carrier. Thereafter, PMA worked diligently to reach a compromise

that would appropriately continue to allow company representatives to distribute drug samples to physicians who request them, but with strict restrictions. Our industry, Chairman Dingell and other key members of the House Energy and Commerce Committee almost reached agreement at the end of 1986, but were unable to do so before the 99th Congress adjourned. This year, we moved quickly to resolve our remaining differences, and on March 12, 1987, the PMA Board of Directors unanimously approved the sampling provisions in H.R. 1207.

H.R. 1207 incorporates, in Section 5, the Voluntary Code for Prescription Drug Sampling Practices adopted by our industry last fall. The Code (a copy of which is attached to my testimony) covers the proper distribution of samples, storage, disposal, inventory and record keeping. Our companies, to the extent they were not already following the practices set forth in the Code, began to implement its provisions at once.

The House bill permits representatives of pharmaceutical companies to continue to distribute drug samples to physicians, under clearly defined and controlled conditions. The legislation includes civil penalties of up to $1 million for companies whose employees divert drugs.

Specifically, H.R. 1207 requires that companies whose representatives distribute samples to physicians:

- Obtain a written request from a practitioner licensed to prescribe drugs specifying the name of the drug and the quantity of samples desired.

- Provide proper storage conditions for samples.

- Conduct an annual inventory of the samples held by sales representatives.

- Maintain sample distribution records for three years.

- Maintain a list of the names and addresses of sales representatives and the sites where they store their samples.

- Make their records available to the Secretary of the Department of Health and Human Services on request.

- Notify the Secretary of the Deparment of Health and Human Services of the significant loss or theft of samples.

- Notify the Secretary of the Department of Health and Human Services of any conviction for the sale, purchase or trade of a drug sample.

The House Committee Report makes clear, however, that

pharmaceutical manufacturers are not to inquire into the use of samples by a practitioner, or intrude in any way into the physician/patient relationship. "Specifically," the Report states, "the Committee does not intend to impose upon a manufacturer or distributor any responsibility to investigate the practitioner recipient of samples."

The House legislation places significant burdens on those pharmaceutical companies that decide to continue to use representatives to distribute drug samples to physicians. These provisions were not accepted hastily or lightly by our industry, but were worked out in lengthy discussions and negotiations. We strongly believe this compromise best serves the interests of patients and physicians--by continuing to permit company representatives to distribute drug samples to physicians, under clear and controlled circumstances--and we urge that H.R. 1207 be sent to the President without amendment.

Mr. Chairman, that concludes my statement. I would be pleased to respond to any questions you or other members of the Subcommittee may have.

Senator MATSUNAGA. I appreciate both of you taking time out of your busy schedules. Can you tell the subcommittee how the drug diversion affects pharmaceutical manufacturers under present law? In what manner adversely are you affected? And under present law, are you able to control it? Or are you here testifying in support because you actually do need this new law in order to manufacture drugs and have them distributed as they ought to be?

Mr. MOSSINGHOFF. Mr. Chairman, for PMA, I would respond that we need the new law. The major provisions of it are very important to the manufacturers. As an example, the American goods return provision that requires that only under very exceptional circumstances goods originally sent abroad can be brought back into the United States, they can be brought back now presumably to anyone. Under the law, they could be brought back only to the manufacturer and only for disposition.

That is an important provision and we think it cuts off an area of a diversion market which should not exist. The cases of counterfeiting pharmaceutical products have not been widespread. We were aware of the examples cited this morning. From 1981 until 1985, I was pleased to serve as U.S. Commissioner of Patents, and I headed up a task force in The White House which resulted in the Counterfeiting Act that was enacted three years ago, which puts very stringent criminal penalties as an amendment to Title 18.

At that time, we looked for examples that we could use to convince the Congress that it was an appropriate act to be enacted and found almost none in the pharmaceutical area. The Ovulin 21 example that was cited, the birth control pill example; since then, we are aware of a couple of other cases, but nevertheless the danger exists.

And we think by cutting off this diversion market that the Congress will be doing a great service to further ensure that there are no counterfeit products reaching American consumers.

Senator MATSUNAGA. Mr. Desmond, do you have any comment?

Mr. DESMOND. NPA would concur with Mr. Mossinghoff's comments, and seeing something like this would upset anyone. However, if I may just reiterate, the small companies support the bill, but we do need to maintain our ability to sample products. That is really our only way to reach the physicians.

Senator MATSUNAGA. You have heard the others testify that they favor the language of the House bill. You suggested certain amendments to that House bill. Did I understand you to suggest a change in the language of the statute, or is that an addition to the report language?

Mr. DESMOND. Yes. We do not suggest any change at all to the bill, but rather adjustments to the report language.

Senator MATSUNAGA. I see. All right. Thank you very much, both of you.

Mr. MOSSINGHOFF. Mr. Chairman, if I may make one last comment?

Senator MATSUNAGA. Yes.

Mr. MOSSINGHOFF. Mr. Desmond and I chatted last week about their proposal to change the report language. I want the record here to be very clear that PMA in a long and arduous compromise came up with the provisions of H.R. 1207 that is, Chairman Din-

gell's provisions. We brought it to our Board of Directors, and they unanimously accepted that as a very important piece of legislation to be enacted. We recommend no changes to the provisions and no changes to the report construction of those provisions.

Senator MATSUNAGA. That is the House bill you are speaking of?

Mr. MOSSINGHOFF. Yes, Mr. Chairman.

Senator MATSUNAGA. All right. Thank you again, both of you.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

Mr. DESMOND. Thank you.

Senator MATSUNAGA. The subcommittee stands in adjournment, subject to the call of the chair.

[Whereupon, at 3:45 p.m., the hearing was concluded.]

[By direction of the chairman the following communications were made a part of the hearing record:]

Statement by Paul B. Simmons, President, Health Industry Distributors Association, For the record of hearings on S. 368, International Trade Subcommittee, Senate Finance Committee, June 15, 1987

The Health Industry Distributors Association welcomes this opportunity to comment on S. 368, the Prescription Drug Marketing Act, on behalf of its more than 1,500 members and branch offices.

Our members provide the full range of medical supplies and equipment to our nation's hospitals, physicians, and other health care providers. While medical devices account for the greatest volume, our members also distribute drug products to hospitals, most notably the intravenous solutions used in great quantity in treating hospital inpatients. The re-sale and diversion of these medical supplies by hospitals -- whether re-sold to intervening re-sellers or directly to physicians -- is in our view a major problem, risking serious consequences to the safety of our nation's hospital and medical distribution system.

We therefore support S. 368, which should bring an end to the re-sale of bulk prescription drugs and of intravenous solutions, which are classified as drugs.

We believe, however, that S. 368 is seriously flawed in omitting to proscribe the diversion of medical devices. The economic and the safety issues raised at these hearings concerning diversion of drugs apply in parallel to the diversion of devices. We urge the Congress to investigate this situation, to hold oversight hearings, and to extend provisions similar to those of S. 368 to the diversion of medical devices. This could be done through revision of the Medical Device Amendments of 1976, as are now being considered by the House of Representatives, or through separate legislation.

Robert L. Barr, Jr., United States Attorney for the Northern District of Georgia and other witnesses have already explained to the subcommittee how prescription drugs are available to hospitals at deep discounts from their normal wholesale price. These discounts would be prohibited by the Robinson-Patman Act except for the special dispensation of the Non-Profit Institutions Act. That exemption was intended to cover only products for the hospital's own use. The American Hospital Association has concurred that this exemption from the Robinson-Patman Act precludes re-sales outside the "own-use" exemption. Nonetheless, such re-sales by non-profit hospitals have become commonplace.

Under the Non-Profit Institutions Act exemption, manufacturers of medical devices also provide non-profit hospitals with deep discounts similar to those provided by drug manufacturers. The prices are often so low that the non-profit hospitals can easily re-sell these supplies at prices below those the wholesale distributor can obtain, even when he buys from the manufacturer in a quantity as great. These re-sales are commonly made to re-sellers -- often called diverters -- or to physicians who are house staff.

Richard Allen, Senior Agent of the Drugs and Narcotics Agency of the State of Georgia has told this subcommittee that diverters who cannot safely divert drugs will divert medical devices. Both his testimony and our members' experience shows that this is already happening. Does the Congress intend to sanction this? Of course not.

Let us provide the following example, from a case where prosecution has been completed. In testimony in July, 1986 before the Subcommittee on Oversight of the Energy and Commerce Committee, Richard Allen and Tom Mras, Manager of Corporate Security at Becton-Dickinson and Company, described the operations of Marchar Laboratories, one of several firms indicted for fraud in placing orders for diverted drugs. The firm pleaded guilty to mail fraud and we believe the firm is no longer in business. As developed in that testimony, Marchar carried out many of its re-sales through a subsidiary firm known as Med-Ped. Before the indictments for drug diversion drove it out of business, Marchar/Med-Ped was also offering medical devices for resale. We are providing for the record of the hearings several representative pages from one Med-Ped price list offering sterile medical devices and intravenous solutions for sale.

In cooperation with the manufacturer of one brand of these products, one of our members placed an order with Med-Ped. The product arrived with the name of the original consignee obliterated. Other members have received offers of re-sale from other firms. Another member placed a similar order with a second firm which may have been a diverter. These products arrived with information indicating the original consignee has been outside of the United States. This information has been provided to the proper authorities for investigation.

Prosecution to date for diversion of drugs has been under mail fraud and related statutes. But, as other testimony before the Committee made clear, the root of the problem is the creation of the two-tier deep-discount price system made possible under the Non-Profit Institutions Act Exemption from the Robinson-Patman Act.

Congressional intent in passing the Robinson-Patman Act was clear: to ensure a level playing field for all businesses, big and small, at a time when predatory pricing and market domination were rampant.

Equally clear was Congressional intent in enacting the companion Non-Profit Institutions Act which effectively exempted non-profit hospitals and other charitable organizations from Robinson-Patman in the case of products they might purchase for <u>their own use</u>.

The idea was to permit non-profits to obtain discriminatorily low prices from vendors to lower their overhead and thus extend the reach of their services to those unable to afford such services on their own.

These Acts were passed at a time when a "charitable" hospital was largely just that -- a private institution whose charter included caring for the poor and the old and infirm who had no private means, personal or insurance, to pay for it. There was, of course, no such

thing as Medicare or Medicaid or any other of the scores of Federal and State programs that have been put in place since that time.

Today, thanks to Medicare, Medicaid and private sector health insurance, that bottom line for non-profit hospitals is far closer to that of a private, profit-making hospital -- and yet still the discriminatory prices are available. Still they are used. And, most significantly, now they are being abused as some of these hospitals scramble to find new ways to stretch their dollars and improve their bottom lines in the wake of the 1983 implementation of the Medicare prospective payment system.

Here's a typical scenario of what is happening in the marketplace:

-- A hospital takes advantage of its Non-Profit Institutions Act exemption from Robinson-Patman and purchases medical equipment and supplies far in excess of its own needs at prices that can be as much as 40 per cent below the prices a private sector wholesaler-distributor must pay for those same products.

-- The hospital then re-sells some of those products to doctors and clinics and individuals in its community, sometimes making a handsome profit, at other times selling at or near its cost as a way to curry favor with doctors on its staff to ensure those doctors will refer patients to the hospital from their own private practices and clinics.

-- Or, the hospital might also re-sell those products on the fast-growing "gray market" operated by unscrupulous firms that specialize in acquiring deeply-discounted products for re-sale to any and all customers. This "gray market" in medical products and devices exactly parallels the "gray market" in drugs described by other witnesses before your Subcommittee.

Is this legal? No. Not under terms of the Non-Profit Institutions Act and subsequent court and Federal Trade Commission rulings which sharply limit which goods can be resold to whom. The law says: to enjoy the Non-Profit Institutions Act exemption, discriminatorily priced medical products can be bought solely for the hospital's own use or for the personal use of its patient and staff and their staff's families. If the exemption is not planned to protect the original deep discount to the hospital, the discount must otherwise meet a Robinson-Patman defense to be lawful. The exemption and the defenses cannot possibly justify and protect many of the deep discount and diversion situations we see out there.

Such re-sales of deeply-discounted products are for reasons far afield from Congressional intent. Such re-sales do nothing to cut the hospital's operating costs -- unless the hospital profits from them -- but they do much to undercut the private marketplace.

What are the consequences for government? For manufacturers? For hospitals? For private sector distributors? And, most important of all, for the patients all of us are supposed to be serving?

For government, the fall-out is obvious: in falling-off of tax revenues, in gross violations of the Non-Profit Institutions Act and Robinson-Patman Act and in transactions contrary to FTC rulings.

For manufacturers and hospitals alike, there is not only exposure to prosecution -- for both the seller and the buyer may be jointly liable in certain cases of illegal re-sales -- but also the gradual erosion of the nationwide system of distribution of medical care products and devices. For 200 years, our industry has served the health care system well. Indeed, the system of distribution that has evolved over history is one of great unsung assets that has ensured that quality products are delivered to those responsible for quality care.

For distributors, the implications are obvious. They are increasingly finding that the "level playing field" envisioned by the Robinson-Patman Act is becoming a tilted arena in which they are expected to compete wearing blindfolds with an arm tied behind their backs.

For patients, the implications are less obvious but no less serious.

For example, when medical care devices and products flow into the private marketplace through "back-door" re-selling by hospitals, what happens to the traceability of those products in the event of a manufacturer's recall? As noted by Robert Barr, U.S. Attorney for the Northern District of Georgia at these hearings, "diversion jeopardizes the ability to trace drugs in the event of a product recall since the drugs are not used by he entity for which they are ordered." Each year, hundreds of devices and products are recalled to prevent injury to patients by dint of problems with sterilization, efficacy, operation and so on -- the same kinds of reasons that compel the recalling of drugs.

The normal distribution chain -- from manufacturer to distributor to provider -- has achieved a remarkable record on recalls of potentially dangerous products. When that chain is broken, as is happening with illegal re-sales, so is the capacity to build on that remarkable record.

In his testimony before this Committee, Richard Allen of the Georgia Drugs and Narcotics Agency stated that "We've found an increase in the number of needles, syringes -- the various medical devices -- being diverted.... Marchar had a booming business in medical devices, and these products were diverted from the same type sources as their drugs.... These diverted medical devices can be just as much of a hazard to the American public as are the diverted drugs."

And Allen warned, "Some drug diverters are turning to exclusively diverting these devices, in an effort to keep from coming under the scrutiny of diversion investigations. But again, as with the drugs, the integrity of these medical devices cannot be assured once they have been outside the normal distribution network."

I would not want to be the father or grandfather or a child who receives an injection or an intravenous solution through a contaminated needle or IV delivery set that had gone through a twisted and extended chain of distribution. Violations of the Robinson-Patman Act pale in comparison to the safety risks at issue.

What about costs? Are such re-sales passing on discriminatorily low prices to the patient at the doctor's office or clinic? Hardly. In fact, exactly the opposite may be happening out there. Health care cost inflation is still far above inflation in other sectors of the economy.

Finally, what might Congress and the industry itself do?

First, in hearings June 26 before the Oversight Subcommittee of the House Ways and Means Committee, we urged that the IRS take a long and hard look at those non-profit entities which set up ostensibly for-profit subsidiaries and claim they are paying their full and fair share of taxes.

In the case of non-profit hospitals, for example, which choose to re-sell products through such a for-profit entity, one key question is: did the parent non-profit corporation buy the products at a Non-Profit Institutions Act discount? If so, the transaction should be unlawful: both the deep-discounted original purchase by the hospital, and also the for-profit's purchase, even if at cost, since the for-profit is then masquerading as an entity which can buy at non-profit discounted prices.

Second, we recommend that Congress act to prohibit any re-sales of medical care products by any hospital just as it is now moving to enact a similar injunction against the re-sale of drugs. As noted above, both the economic and the safety issues involved in diversion of devices are as great as in diversion of drugs. The risks to patient's health are too great to ignore any longer. Richard Allen's comments at your hearings on diversion of needles and syringes should send a chill up the back of everyone of us -- and a message on which Congress should act. Recognizing the reluctance of this Committee to open the House-passed legislation to amendment at this time, we urge the Congress to review the issues of device diversion, next year if necessary, in context of pending changes in the Medical Device Amendments.

Third, we believe Congress could do much to forestall endemic abuse of the Non-Profit Institutions Act throughout the non-profit sector if it were to squarely clarify the jurisdiction of the Federal Trade Commission over non-profit organizations. The murkiness in present law on this pivotal issue makes it all the tougher for the FTC in particular and the Federal government in general to move quickly and effectively on abuses of the system.

The private sector should not have to keep appealing to the courts to adjudicate wrongs it suffers at the hands of non-profit entities which take advantage of the relative enforcement vacuum that now

exists in this area. We believe Congress should make the law more clear and thus make such onerous and expensive court cases unnecessary.

Fourth, the industry itself can do more to police its own operations under extant law. For example, we have requested a Federal Trade Commission staff legal advisory opinion to permit a cross-section of HIDA members to meet with their counterparts from among the manufacturing community to see if we can arrive at a consensus on this issue. HIDA, for one, would like to see more manufacturers follow the law with permissible "no re-sale" clauses in their contracts with hospitals. According to the trade press, several leading manufacturers have already adopted this approach. We also applaud the recent action by the Health Industry Manufacturers Association (HIMA) to mount a member education campaign designed to acquaint its 300 members with the legal perils associated with illegal product resales and with methods they might use to combat the practice. We would also like to see all hospitals pay more than lip-service to the restrictions of the Robinson-Patman and Non-Profit Institutions Acts.

Since we launched an industry-wide campaign earlier this year to alert manufacturers and hospitals to the provisions of current law and their potential liability should they violate those laws, we have seen signs of changes in behavior out there in the marketplace. Many hospitals have stopped the practice of illegal re-sales. Others have stopped short of entering the practice.

But many are flouting the law on the assumption they won't be prosecuted, and in some cases, they may indeed be lucky enough to avoid the kinds of suits many of our members are contemplating.

Do we want diverters to turn from drugs to devices, as could happen if Congress explicitly rules that drug diversion is illegal but is silent on device diversion? Of course, that is not the message this Subcommittee or the United States Senate wishes to send to diverters and their sources of supply.

Fix the law, make violators certain targets of punishment and you will have done a great service to our industry and the patients we serve.

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November 16, 1987

Senator William V. Roth, Jr.
United States Senate
104 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Roth,

I am writing to you in response to your questions, which are to be inserted in the hearing record for S.368, June 15, 1987. Your questions, along with my answers, are as follows:

Senator Roth: In addition to the diversion of drugs, have you seen other health care industry products diverted that could pose a threat to the public health? If so, to what extent is it a problem?

Allen: Yes sir, I am afraid I have seen quite a lot of non-drug health care products being diverted. And these products are handled by the same people which are dealing in diverted drugs. And handled in the same, unauthorized manners in which the drugs are handled. Non-drug products are valued as much as drugs in the diversion market. And, it would be just as simple, even more so, to introduce counterfeit products into the market as legitimate health products, just as it is with drugs. And due to the fact that at this point, no one is interested in prosecuting or even investigating health product diversion, there exists a frightening potential increase in the diversion of all health care products. And with this increase in diversion, a similar increased potential threat to public health.

Senator Roth: Do you see any parallels between the diversion of drugs and sterile products?

Allen: Yes sir, in fact so much of a parallel, that if you look only at the quantities and dollars involved, there is literally no difference in the two. The prices given on sterile products vary enough so that they make these products very attractive to diverters. I have seen many diverters setting up new divisions, or complete new companies, just to handle sterile products. And, as I previously stated, since the emphasis on diversion investigation/prosecution lies with drugs, the sterile product market is made that much more attractive to the diverters, with the fear of getting caught not being a nagative, business factor.

Thank you for taking the time to express an interest in the diversion issues. The American public will be safer and healthier once this bill is passed and becomes law.

Sincerely yours,

C. Richard, Allen, Senior Agent